

FILED
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U.S. DISTRICT COURT E.D.N.Y.

★ DEC - 8 2021 ★

LONG ISLAND OFFICE

Andrew Kosiba
Plaintiff *in Propria Persona*
33 Neal Path
South Setauket, NY 11720
ak764@protonmail.com

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

225 Cadman Plaza East, Brooklyn, NY 11201

ANDREW KOSIBA
PLAINTIFF

CV-21 6416

CASE NO. _____

v.

CATHOLIC HEALTH SYSTEMS OF
LONG ISLAND, INC.
DEFENDANT

BROWN, J.

LINDSAY, M.J.

AFFIDAVIT IN SUPPORT OF COMPLAINT

STATE OF NEW YORK)
) Ss
COUNTY OF NASSAU)

230. I, Andrew Kosiba, do hereby solemnly affirm that the statements herein are true and correct in substance and in fact and that I have personal knowledge of each.

1 **231.** I have been harassed at my job, discriminated and retaliated against
2 based on disability for refusing to accept my employer's accommodations for
3 regarding me as impaired in my immune system and impaired in my respiratory
4 system.

5 **232.** I am absent and without evidence of any information from any health
6 officer identifying myself as having any communicable disease or having been
7 exposed to any toxic substance.

8 **233.** I am absent and without knowledge of any evidence or court order,
9 obtained by any petition of the Department of Health or a public health officer,
1 that was based upon any physician's affidavit in which I have been identified as
0 having any communicable disease or having been exposed to any toxic
1 substance.

1 **234.** I am absent and without knowledge of any evidence of any court order
2 determining that I am or have been a direct threat to anyone.

1 **235.** I am absent and without knowledge of any evidence of any individualized
3 assessment required by law that has determined that I am or have been a direct
1 threat to anyone.

2 **236.** I am absent and without knowledge of any evidence of any court order
5 imposing any terms of isolation or quarantine or other measures upon myself.

1 **237.** I have previously and timely disclosed and duly noticed the defendant of a
6 prior existing disability, and that the assertions made in the complaint are true
1 and correct to the best of my knowledge, information and belief.

7 **238.** I have been working as a home physical therapist for approximately 20
1 years with Catholic Health. I have never had an issue with management and
8 have been an exemplary employee and I feel I am an asset to the company.
1

1 **239.** When Covid started, there were certain mitigation measures that were
2 instituted like PPE wearing, daily temperature checks, mask wearing, PCR tests
3 which I did in the beginning because no one knew what was happening and I
4 thought it was for my protection as well. As I researched and as time went on
5 and the "numbers" went down these measures didn't go away and I began to
6 research actual scientific data. I started to disagree with the measures we were
7 mandated and saw that more and more we were following political rules for some
8 reason and not science.

9 **240.** Catholic Health requested me to take EUA injections as a job requirement
1 (new condition) in early September. I wanted to opt out of this new policy
0 requirement. I was given a declination form in early September 2021 which only
1 had medical or religious exemptions listed, it did not have an option for refusal
1 based upon informed consent or any other rights protected under the ADA.

2 **241.** I felt coerced and intimidated by the company to get the EUA injections.
1 The company was also classifying me as unvaccinated keeping track of my
3 injection status which felt threatening as I thought they were going to fire me for
1 claiming my rights. I felt very threatened. Despite filing a declination form I
4 continued to receive many emails about where and when I could get the shot.

1 **242.** On March 15, 2021, I was in a GoToMeeting which was run by Dr. Kranz.
5 Dr. Kranz stated that our agency had a 62% compliance with the jab and she
1 said, "That's not enough people, that's not nearly enough!"
6

1 **243.** Most recently during our last in office meeting, I came into the office and
7 noticed many people not wearing masks. I began to take my mask off, but was
1 told to keep my mask on because I was unvaccinated. I was singled out, and
8 this made me feel angry and stressed. I was being segregated and they were
1

1 openly classifying me as unvaccinated and disclosing my medical information to
2 everyone in the room. I felt like a second-class worker.

3 **244.** I have been told by Christine Bracco in HR that I must have an EUA
4 injection by October 7 or I will be fired. My declination is no longer honored and
5 my employer does not acknowledge any right to refuse under the ADA. I am
6 feeling severe anxiety and stress about this. I am having heart palpitations.
7 Night after night I awake at 4 o'clock in the morning and cannot fall back asleep
8 because of these measures.

9
1 **245.** On August 16, 2021, I was not feeling well and spiked a fever. I called out
0 sick and under duress because of all the hype of the virus I took a home PCR
1 test which was positive. When I called the agency, I was told that because I
1 tested positive for Covid they were going to notify all patients I came in contact
1 with for 3 previous days. I was furious. I thought, "How can they share my health
2 information like that?". It made me extremely anxious. They said they would not
1 name me. This was not good enough! Due to the nature of my job I sometimes
3 am the only clinician visiting the patient and I was even told by the nurse at work
1 (Christina Nelson) that I should be ready that some people might "figure it out".
4 I have an excellent rapport with my patients, and I felt that this was a betrayal.
1 Ironically, 3 days later I tested negative with a PCR test.

5
1 **246.** On September 28, 2021, I arrived to the office for a meeting. Upon arrival
6 I was forced to have a temperature check before going in. When I asked if this
1 is necessary because I had already sent in a temp check to my supervisor that
7 morning and was clear. I was told I must comply. After doing it I remarked that
1 this is redundant and upon walking away I heard one of the ladies at the front
8 desk say, "That's one of the ones who will be leaving".

1 **247.** On September 30, 2021 I was at a monthly meeting for my team and was
2 informed that whoever was vaccinated will receive a sticker to wear on their
3 badge so they will be identified as such. I was made to feel so excluded,
4 intimidated and made me feel very anxious as to how far this would be taken.

5 **248.** On October 16, 2021 I saw that a patient that was assigned to me had a
6 "Vaccinated Staff Only" stipulation on their file. I was very disheartened and
7 saddened to see that Catholic Health was following such a discriminatory policy.
8 Not only is it revealing my health information when I have to decline such a case,
9 it also discriminates against me in my professional capacity. Instead, I feel that
10 Catholic Health should educate the patient that they cannot discriminate on the
11 basis of disability and that they cannot enforce such a policy. This would not be
12 tolerated if a patient requested any other discriminatory request.

1 **249.** On November 5th I received an email stating that I am to be required to
2 have a bi-weekly COVID test as the agency is waiting on rulings from lawsuits
3 regarding religious exemptions. I am very stressed about this as I have never
4 been required to take a COVID test while I am healthy. I have not been informed
5 of the efficacy of the PCR tests nor of the long-term effects of frequent testing. I
6 want to be left to do my job as I have been doing for over twenty years, including
7 the past two years during this "pandemic".

8 **250.** On November 17, 2021, I received an email from Christine Bracco and
9 Tony Pellicano, Chief HR Officer stating that if I don't receive an injection by
10 November 22, 2021, I will be placed on leave without pay for 2 weeks. I have
11 had a vacation planned for weeks which happened to coincide with the
12 November 22 date. After that time employees who still have not received the
injection will be terminated.

251. On November 28, 2021, after returning from vacation, I had received a letter from Christine Bracco Bracco, Director of Human Resources. The letter stated that I was being placed on "unpaid furlough" for 2 weeks at which point it would be assumed that if I didn't comply with "mandate", that it would be considered that I have resigned. This is outrageous as I had previously stated that I was healthy, ready and able to work. Just as it is a proven fact that "vaccinated" people can become sick from and transmit Covid-19, yet I and others who refuse the "vaccine" are the only ones in danger of being terminated. This is causing a severe amount of anxiety to me and my family. I am having heart palpitations and nausea because of this latest policy. I feel like I am experiencing and being continually discriminated against. All I want to do is return to my job without prejudice and do what I am more than capable of doing. The documents included with Exhibit A are true and correct copies of the originals.


Andrew Kosiba, Affiant

STATE OF NEW YORK)
) Ss
COUNTY OF NASSAU)

Subscribed and sworn to before me a notary public this 7th day of December, 2021.



Signature of Notary

[Is]

DREW D. CASS
NOTARY PUBLIC, STATE OF NEW YORK
Registration No. 01CA6298761
Qualified in Suffolk County
Commission Expires March 17, 2022

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EXHIBIT A

written communications



Fw: Message on behalf of Alan Guerci, M.D.

1 message

Kosiba, Andrew <Andrew.Kosiba@chsli.org>
To: ak764@optonline.net <ak764@optonline.net>

Thu, Apr 8, 2021 at 3:50 PM

From: Cudahy, Maryann
Sent: Friday, December 11, 2020 10:35 AM
To: Email Users - All
Subject: Message on behalf of Alan Guerci, M.D.

Dear Colleagues,

I know many of you have questions regarding a COVID vaccine. I am happy to inform you that the F.D.A.'s vaccine advisory panel, voted in favor of emergency authorization for people 16 and over. Although the F.D.A. does not have to follow the advice of its advisory panel, it usually does. Emergency Use Authorization (EUA) should follow by this weekend. Although the vaccines will not be widely available to the general public for many months, Pfizer and Moderna have produced enough doses for approximately 20 million people. These first doses will go to people in high-risk groups, including health care workers.

We expect to receive our first batch of vaccines the week of December 14th. CHS employees will be offered the vaccine based on risk of exposure to COVID-19. Top priority will be given to employees and physicians in our ICUs, emergency departments and dedicated COVID units, as well as long-term care, home care and hospice workers who regularly interact with patients and residents. We will make the vaccination more widely available as additional supplies are received. For more information, please refer to the attached FAQs and our COVID Vaccination Policy<http://chsli/assets/system_wide_policies/COVID%20%20MERS%20SARS%20Co%20V%20Vaccination%20Policy.pdf>. Patients will be treated following a separate protocol.

While we are not making the vaccine mandatory at this time, we strongly urge all caregivers to be vaccinated. Please know the vaccine requires two doses. More information will be shared as the vaccine becomes more widely available. Meanwhile, we have prepared a comprehensive FAQs that we hope answers your questions. To address your concerns, we will be establishing a hotline in the near future so you can ask questions about the vaccine that are not addressed by the FAQs. Responses to your questions will be posted on the CHS intranet so that they are available to all employees.

Some of you may be apprehensive about receiving a COVID-19 vaccine. It is important to note that during Phase III trials, the vaccines showed better than 95% effectiveness with no serious adverse safety concerns. As health care providers, we have an obligation to lead the way for our patients, ourselves and our families, which is why I will be one of the first to be vaccinated. An effective vaccine will keep us safe and will be essential to putting this pandemic behind us.

Maryann Cudahy

Assistant to Alan D. Guerci, M.D., President & CEO

Assistant to Salvatore F. Sodano, Chairman

Catholic Health Services of Long Island

992 North Village Avenue

Rockville Centre, NY 11570

(516) 705-3708

maryann.cudahy@chsli.org<mailto:maryann.cudahy@chsli.org>

[CHS_Logo_Revise_4C_Tagline cropped]



Fw: COVID Survival Tip #1

1 message

Kosiba, Andrew <Andrew.Kosiba@chsli.org>
To: ak764@optonline.net <ak764@optonline.net>

Thu, Apr 8, 2021 at 3:44 PM

From: Frawley, Mary
Sent: Tuesday, January 5, 2021 7:45 PM
To: Email Users - Catholic Home Care
Subject: COVID Survival Tip #1

Dear Staff,

The attached article is about disconnecting from the electronic world during COVID. We have had so many challenges during the past 9 months. This article reminds me that it is important to disconnect, go outside and get some fresh air and remember that we will survive COVID!!!

Take some time to read, think about disconnecting and spending some quality time with your family and GET VACCINATED!!!

Stay Safe,

Mary

Mary Frawley DNP, RN

Director of Patient Services

Catholic Home Care

110 BiCounty Blvd Ste 114

Farmingdale, NY 11735

Ph: 631-828-7408

Email: mary.frawley@chsli.org<mailto:mary.frawley@chsli.org>



Fw: Agency/COVID-19 Update – January 17, 2021

1 message

Kosiba, Andrew <Andrew.Kosiba@chsli.org>
To: ak764@optonline.net <ak764@optonline.net>

Thu, Apr 8, 2021 at 3:45 PM

From: Kranz, Kim
Sent: Sunday, January 17, 2021 10:08 AM
To: Email Users - Catholic Home Care; Email Users - Good Shepherd Hospice
Cc: Verzi, Dennis
Subject: Agency/COVID-19 Update – January 17, 2021

Message sent on behalf of Kim Kranz, President

As this week comes to a close, I'd like to reflect on our vaccination initiatives over the past several weeks and thank all of those involved for the work they have done to provide this much needed service to our employees. To date 455 of our employees have received the vaccination, this is only 50% of our employee base. Dr. Kerriane Page, CMO and myself continue to communicate the importance of vaccinating all. We highly recommend and encourage you to be vaccinated for the protection of yourself, your loved ones, our patients/families and your fellow employees. Please work with Chris Bracco, HR Partner, to schedule your 1st dose of the vaccine.

Dr. Page is available to discuss any questions or concerns you may have about receiving the vaccine.

As eligibility requirements for the COVID vaccine expand it will become more challenging for us to have supply.

Now is the time to work on scheduling an appointment.

In addition, I am excited to share the launch of the new system name of Catholic Health! Over the next few weeks, you will continue to see messaging relating to this new branding, as well as the launch of our new system logo on January 27. Following that release, there are a number of other branding changes that will continue to be mentioned throughout the system. Continue to visit our social media pages for the latest information on our new brand launch.

Below are some important highlights for all staff that I would like to share with you:

COVID

Our hospital(s) goal is to keep COVID volume at the appropriate levels so our system can continue to perform elective surgical procedures. We have been working with our hospitals closely to ensure patients are safely transferred to their homes.

Currently we are caring for over 250 patients who are COVID positive or a person under investigation (PUI). I want to thank all our employees and volunteers who are keeping our staff safe by ensuring protective equipment is ordered, inventory is tracked & maintained, supplies are packaged and supplies are distributed, remarkable teamwork!!

COVID update calls with Dr. Page, our program Directors and myself will continue during the week of January 25th.

ACUTE HOSPITAL AT HOME PROGRAM

A new innovative model of patient care, the acute Hospital At Home program is scheduled to launch next week. This program has been approved by Center for Medicare and Medicaid Services (CMS) for all six hospitals. A multidisciplinary group of leaders have built a level of quality and safety to patients who qualify for the Catholic Health Hospital At Home program. This care allows for a select set of COVID-19 patients who would most benefit from the opportunity to continue their acute hospitalization at home. A strict inclusion criteria will be used and patients identified will receive their continued Remdesivir infusion therapy at home. Over 40 of our clinicians from Home Care are trained in this new model of care.

I would like to thank all of the clinicians involved in delivering this new model of care and level of service.

A special thank you to Dr. Page and Barbara Rowe for their unwavering leadership and support of launching and operationalizing this program.

In closing, I would like to share with you a prayer from Catholic Health Services:

Lord grant that our lives may amaze. Make us staunch advocates of the freedom you proclaimed in the synagogue in Nazareth and tirelessly work to bring your glad tidings to the poor.

Thank you for delivering our mission and ministry to serve our communities.

With gratitude,

Kim

9/20/21, 8:47 AM

Gmail - Fw: Message on behalf of Tony Pellicano / Re: NYS Vaccination Mandate



Andrew Kosiba <kosproducts@gmail.com>

Fw: Message on behalf of Tony Pellicano / Re: NYS Vaccination Mandate

Kosiba, Andrew <Andrew.Kosiba@chsli.org>
To: "ak764@optonline.net" <ak764@optonline.net>

Fri, Sep 3, 2021 at 5:32 PM

From: Dolan, Sarah
Sent: Thursday, September 2, 2021 1:46 PM
To: AllCHSLIEmailUsers
Subject: Message on behalf of Tony Pellicano / Re: NYS Vaccination Mandate

I write with an important update on the New York State COVID-19 vaccination mandate for covered healthcare workers and the accompanying Catholic Health policy, which is required by the New York State mandate. On August 26, 2021, New York State issued regulations requiring COVID-19 vaccinations for all covered healthcare workers in the state. These regulations eliminated the availability of religious exemptions for covered healthcare workers. The New York State Department of Health cited public health reasons for the elimination of religious exemptions and noted that New York State has existing vaccination requirements for healthcare workers, such as for measles, which are not subject to religious exemptions.

As a health care institution in New York State, Catholic Health is required to follow Department of Health mandates. Therefore, Catholic Health entities will not be able to consider requests for religious exemptions and will only be able to consider requests for medical exemptions based on pre-existing conditions. All covered healthcare workers who do not receive an approved medical exemption will have to receive at least one dose of the COVID-19 vaccination by the State deadlines of September 27, 2021 (for hospital and nursing home staff) and October 7, 2021 (for staff of home health, hospice and diagnostic and treatment centers).

A copy of Catholic Health's revised COVID-19 Vaccination Policy, which is in compliance with regulations, is attached and includes the Catholic Health form for requesting medical exemptions. The form is also posted on the Catholic Health intranet. Please note that all requests for medical exemptions must be submitted by Monday, September 20th so we have enough time to review the request and ensure employees are eligible to report to work on the applicable deadline.

Thank you for your attention to this important matter.

Tony Pellicano
Chief HR Officer

(516) 705-3716

tony.pellicano@chsli.org <mailto:tony.pellicano@chsli.org>



Fw: New York State COVID Vaccine Mandate

1 message

Kosiba, Andrew <Andrew.Kosiba@chsli.org>
To: ak764@optonline.net <ak764@optonline.net>

Wed, Sep 8, 2021 at 8:01 PM

From: Bracco, Christine
Sent: Wednesday, September 8, 2021 4:36 PM
To: Bracco, Christine
Subject: New York State COVID Vaccine Mandate

I am reaching out to you as a follow up to the recently announced New York State vaccination mandate for Healthcare employees, which will take effect for Home Care and Hospice on October 7th.

For over six years now I have been a proud team member of Catholic Health Home Care and Good Shepherd Hospice and I am inspired and humbled on a daily basis by the incredible work you all do on behalf of our patients and family members. Having had the opportunity to speak individually with many of you, I know this announcement has been distressing and I wanted to reach out to each of you to offer my support as we navigate through this new requirement.

At this time, my records indicate you have not received a COVID vaccination. If that information is not up to date or if you have a scheduled vaccination, please let me know as soon as possible.

If you are considering not being vaccinated, please let me know by the end of this week, 9/10/2021, so I can work towards assisting you with options and/or next steps.

Thank you for all you do!

Chris

Christine Bracco

Director of Human Resources

Catholic Health Home Care/Good Shepherd Hospice

(631) 828-7603 (Tel)

(631) 566-5656 (Cell)

(631) 828-7610 (Fax)

christine.bracco@chsli.org<mailto:christine.bracco@chsli.org>

110 Bi-County Blvd, Suite 114

Farmingdale, NY 11735

9/20/21, 8:46 AM

Gmail - Fw: Hospice & Home Care Agency Update



Andrew Kosiba <kosproducts@gmail.com>

Fw: Hospice & Home Care Agency Update

Kosiba, Andrew <Andrew.Kosiba@chsli.org>
To: "ak764@optonline.net" <ak764@optonline.net>

Fri, Sep 10, 2021 at 7:30 PM

From: Kranz, Kim
Sent: Friday, September 10, 2021 1:58 PM
To: Email Users - Catholic Home Care; Email Users - Good Shepherd Hospice
Subject: Hospice & Home Care Agency Update

GSH/CHC Team Members,

Please allow this to serve as an agency update which includes:

- We will Never Forget
- Current Status – Census & COVID cases
- Recruitment
- Vaccination Plan
- Patient Experience

This Saturday, September 11th in remembrance of 9/11 we will have our Chaplains present in our Farmingdale Office, Port Jefferson and Rockville Centre IPU's to provide our staff with prayer and remembrance for the 20th anniversary of this tragic event.

Current Status – Census & COVID cases (we continue to track and trace daily)

CHC

9/7/2021

9/8/2021

9/9/2021

9/10/2021

Total Census

9/20/21, 8:46 AM

Gmail - Fw: Hospice & Home Care Agency Update

2653

2614

2598

2584

Patient PUI

12

10

11

16

Patient Positive

26

25

27

35

Staff in Quarantine

1

1

1

2

Staff Test Positive

3

1

9/20/21, 8:46 AM

Gmail - Fw: Hospice & Home Care Agency Update

1

2

Hospice

9/7/2021

9/8/2021

9/9/2021

9/10/2021

Total Census

376

372

371

379

Patient PUI

4

4

4

3

Patient Positive

1

1

1

9/20/21, 8:46 AM

Gmail - Fw: Hospice & Home Care Agency Update

4

Staff in Quarantine

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Staff Test Positive

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9/20/21, 8:46 AM

Gmail - Fw: Hospice & Home Care Agency Update

- Please do not come to work if you are sick or experiencing any COVID symptoms.
- COVID testing for non-symptomatic employees is occurring in our Farmingdale office Monday's and Wednesday's 8:00am – 1:00pm

Recruitment

I am happy to announce we have over 30 new employees starting in our September 13th orientation. This includes clinical and support team members in both Hospice & Home Care. A very special thank you to all our Managers and Recruitment Team, Human Resources and Education Team for your positive efforts in making this a possibility. We will have another Open House in September along with daily on-site interviewing for walk-ins. Our October orientation already includes clinicians for both programs.

Vaccination Plan

- Approximately 80% of our staff have been vaccinated.
- If vaccination is received proof of vaccination must be brought to Human Resources.
- CH Policy on Employee Vaccination issued 09.02.2021, please follow and notify Chris Bracco of any questions.
- Requirement by New York State for all staff to be vaccinated with at least one shot by October 7, 2021.
- Operations is working on a Flex & Sustain Plan identifying the impact that non-vaccinated staff will have on each department operations. This will require daily monitoring for needed alterations.

Patient Experience

- We have seen incremental positive results with our overall patient experience scores and have opportunity for improvement to reach our CH goal. Our managers will continue to provide Appreciative Coaching training. We have shared with our management team our most recent scores for July.

Focus on our I-CARE golden key behaviors Every Patient....Every Time makes every encounter a Positive Experience for Our Patients.

THANK YOU for being our Heroes.

Please be careful and safe. I am available if you have any questions.

With gratitude,

Kim

9/20/21, 8:46 AM

Gmail - Fw: Hospice & Home Care Agency Update

Kim Kranz

President

Catholic Health

Home Care and Good Shepherd Hospice

110 Bi-County Blvd. Ste. 114

Farmingdale, NY 11735

T (631) 828-7410

F (631) 828-7494

Kim.kranz@chsli.org

[cid:image001.png@01D7A64B.DEBE7220][cid:image002.png@01D7A64B.DEBE7220]

Vaccination

2 attachments



image001.png
6K



image002.png
8K

9/20/21, 8:44 AM

Gmail - Fw: Message on behalf of Tony Pellicano / Re: NYS Vaccination Mandate



Andrew Kosiba <kosproducts@gmail.com>

Fw: Message on behalf of Tony Pellicano / Re: NYS Vaccination Mandate

Kosiba, Andrew <Andrew.Kosiba@chsli.org>
To: "ak764@optonline.net" <ak764@optonline.net>

Thu, Sep 16, 2021 at 7:08 PM

From: Dolan, Sarah
Sent: Thursday, September 16, 2021 2:38 PM
To: AllCHSLIEmailUsers
Subject: Message on behalf of Tony Pellicano / Re: NYS Vaccination Mandate

Dear colleague,

On September 14, 2021 an upstate federal court granted a temporary restraining order (TRO) prohibiting the State "from enforcing any requirement that employers deny religious exemptions from COVID-19 vaccination." This TRO will go into effect on September 27, 2021. Please note the court ruling does not suspend the NYS COVID-19 vaccination mandate, however it temporarily prohibits New York State from blocking employers from considering religious exemptions. The mandate remains in effect in all other respects. The issue of the availability of religious accommodations is now on appeal to the U.S. Court of Appeals, which has been asked to rule on the State's position on religious exemptions on an expedited basis. A decision from this Court will have binding effect on all health systems in the State, including Catholic Health and its entities.

We continue to receive requests for religious accommodations and will evaluate these once we receive further direction from the courts and regulatory guidance. These requests should be submitted to your local Human Resources department so we can keep accurate track of all that are received. In the meantime we continue to move forward with our plans based on the NYS COVID-19 vaccination mandate. This includes reminding employees about the mandate deadline, providing educational resources and providing ready access to appointments to receive the vaccination.

We will continue to monitor and keep you informed on the status of these legal proceedings and will comply with all applicable judicial orders and regulatory directives. Please know that we will not take any adverse employment actions against an unvaccinated employee seeking a religious exemption from the vaccination mandate while we await further legal and regulatory direction.

Tony Pellicano

Chief HR Officer

(516) 705-3716

tony.pellicano@chsli.org<mailto:tony.pellicano@chsli.org>

9/25/21, 8:16 AM

Gmail - Fw: NY State COVID Vaccination Mandate



Andrew Kosiba <kosproducts@gmail.com>

Fw: NY State COVID Vaccination Mandate

1 message

Kosiba, Andrew <Andrew.Kosiba@chsli.org>
To: "ak764@optonline.net" <ak764@optonline.net>

Fri, Sep 24, 2021 at 6:47 PM

From: Bracco, Christine
Sent: Friday, September 24, 2021 9:07 AM
To: Bracco, Christine
Cc: Verrengia, Michael
Subject: NY State COVID Vaccination Mandate

I hope this email finds you well.

As a follow up to the email distributed by Catholic Health yesterday afternoon, I wanted to reach out to you again with regards to the New York State COVID Mandate.

The New York State COVID Vaccination Mandate for Home Care and Hospice will be effective on October 7th. While an upstate New York federal judge has issued a temporary restraining order prohibiting consideration of religious exemptions, all other vaccine mandates remain in effect. In order to continue working on and after October 7th, employees will need to provide one of the following:

- 1) Evidence of at least the first dose of vaccination. If you have already received your first dose or are fully vaccinated, please send a copy of your NY State COVID card to Jennifer Temple, Employee Health Nurse, as quickly as possible.
- 2) CH approval for a Medical Exemption. Medical Exemption Applications were due on September 20, 2021, so if you are still planning to apply for a Medical Exemption please do so immediately. Medical Exemption applications must be submitted using the CH Medical Exemption Form.
- 3) Religious Exemption; Employees with a Religious Exemption will be permitted to continue working pending CH Committee review and the outcome of the temporary suspension. Religious exemptions should be submitted by today, 9/24, at noon.

Employees who do not meet one of the above criteria will be furloughed, without pay, beginning on October 7th. Employees may only be furloughed for up to 2 weeks, during which time health insurance benefits for you and all covered dependents will be maintained.

Tony Pellicano, our Chief HR Officer, said it best – “we hope we can continue to all work together to ensure that we meet our promise to the patients we serve”.

9/25/21, 8:16 AM

Gmail - Fw: NY State COVID Vaccination Mandate

Please let me know if I can answer any questions or assist you in anyway.

All the best,

Chris

Christine Bracco

Director of Human Resources

Catholic Health Home Care/Good Shepherd Hospice

(631) 828-7603 (Tel)

(631) 566-5656 (Cell)

(631) 828-7610 (Fax)

christine.bracco@chsli.org<mailto:christine.bracco@chsli.org>

110 Bi-County Blvd, Suite 114

Farmingdale, NY 11735

Christine Bracco, Human Resources
Catholic Health
christine.bracco@chsl.org

October 7th, 2021.

RE: Your email on September 24th, 2021.

You (Catholic Health) admit that you do not regard Andrew Kosiba (Andrew) as having any contagious disease, yet you purport to require him to disclose his medical history and submit to medical interventions (accommodations such as mask wearing and vaccines)¹. This violates 29 CFR Part 1630.9(d) and 21 U.S.C. 360bbb-3. You are not exempted from complying with the law under 29 U.S.C. §654.

There are no vaccines during a period of emergency use authorization.

No vaccines have been approved by the FDA and no vaccines are currently in production for the so-called "Coronavirus" or any of its purported derivatives. Your statement that a vaccine has been approved by the FDA is false.

Any medical interventions during an emergency use authorization period are by definition, clinical trials and no one is required to participate in clinical trials for any reason, and certainly not as a condition for employment. 21 CFR Part 50.20.

You state that you have a legal obligation yet failed to cite any legal duty. (What law?). You thereby admit that you have no duty of care or insurable risk to protect employees or anyone from any contagious disease.

You admit that you have no new legal duty of care to protect anyone from any contagious disease. Workman's compensation does not cover contagious diseases. Let me explain the reason for this. First of all, the risk cannot be calculated under any actuarial scheme and secondly, it is statistically impossible to establish the proximate cause of who infected whom.

You provide no supporting facts of any contagious disease but this is not relevant because whether or not there is a contagious disease, or any "pandemic" as you falsely claim, you still have no new legal duty of care, and Andrew Kosiba has no legal duty to disclose his medical records to you. Likewise, he has no legal duty to submit to any of your accommodations (mask wearing, vaccines, or whatever). This is a matter of law, 29 CFR Par. 1630.9(d). **Read the law; and yes, it does apply to Catholic Health.**

You fail to cite any law that exempts you from this actual legal duty, and you fail to cite any law that exempts you from complying with the requirement to conduct an individualized assessment to determine whether Andrew Kosiba is a direct threat to anyone. Commentary and news reports do not satisfy the legal criteria for an individualized assessment.

Please be advised that claiming there is a pandemic is not a legal defense for disability discrimination and retaliation claims. While not relevant, it should be noted that the standard deviation in the mortality rate for the years 2017, 2018, 2019 and 2020 is zero, unchanged. This is the very definition of no pandemic. Moreover, no public health officer, including the CDC, has

¹The FDA defines wearing a mask when intended for health purposes as a medical device. Section 201(h) Food, Drug & Cosmetic Act.

any record of any contagious disease culture or specimen for "Covid-19" or "SarsCov-2" or anything similar, it doesn't exist.

Speaking in pertinent legal terms again, Title I of the ADA prohibits employment discrimination based on disability. Among other things, Title I prohibits employers (you) from requiring medical examinations or making disability-related inquiries of employees unless such examination or inquiry is shown to be job-related and consistent with business necessity; see, 42 U.S.C. §12112(d)(4); 29 CFR §1630.14(c).

Your requests for Andrew's medical records are not part of any job-related employee health program.

You fail to allege any facts that would constitute an undue burden for Andrew's refusal to accept your accommodations.

You fail to allege any fact that would establish any fundamental alteration in the manner in which your business operates. Your policies themselves have created a fundamental alteration in the way your business operates.

You fail to allege facts that the disability you are in fact regarding Andrew as having is not transitory and minor.

Your policies have created a disability for Andrew.

29 CFR Sections 1630.2(r):

"Direct Threat means a significant risk of substantial harm to the health or safety of the individual or others that cannot be eliminated or reduced by reasonable accommodation. The determination that an individual poses a 'direct threat' shall be based on an individualized assessment of the individual's present ability to safely perform the essential functions of the job. This assessment shall be based on a reasonable medical judgment that relies on the most current medical knowledge and/or on the best available objective evidence. In determining whether an individual would pose a direct threat, the factors to be considered include:

- (1) The duration of the risk,
- (2) The nature and severity of the potential harm,
- (3) The likelihood that the potential harm will occur; and
- (4) The imminence of the potential harm."

Your policies have nothing to do with anyone's safety, in fact, your policies violate the safety of your employees and violate your actual duty of care toward those employees. Safety requirements must be based on actual risks (not "guidelines" published on a website) and not on mere speculation, stereotypes, or generalizations about individuals with disabilities.

Since you are not regarding Andrew Kosiba as having any contagious disease and you have no diagnosis or records of the same, you will immediately cease and desist from your illegal conduct of discrimination based upon such a disability and retaliation against Andrew and allow him to do his job without unnecessary interruption. Unless you can show you have conducted an individualized assessment of Andrew and determined that he is a direct threat, by the criteria set forth in the actual law, you will cease and desist from any further communication, harassment, discrimination, intimidation, or retaliation against Andrew.

Re: NYS Vaccination Mandate

From: Andrew.Kosiba@chsli.org <Andrew.Kosiba@chsli.org>
To: Christine.Bracco@chsli.org <Christine.Bracco@chsli.org>
CC: ak764@protonmail.com <ak764@protonmail.com>
Date: Thursday, November 18th, 2021 at 9:14 AM

Hello Christine.

This is my response to Tony Pellicano's email which you forwarded regarding the newest illegal "policy" Catholic Health Services has set forth. Please note that his first point in regards to "all employees in positions such that if they were infected with Covid-19, they could potentially expose other personnel, patients or residents to the disease" also applies to those who were injected or deemed "vaccinated" and yet they are not being fired. Therefore your policy is illegal and discriminatory. I would hope that for the sake of the agency, you would all rethink this policy and return to work as usual without "mandates" which are not law and discriminatory.

Thank you for your attention and please file this again in my confidential file.

Sincerely,

Andrew Kosiba

From: Bracco, Christine
Sent: Wednesday, November 17, 2021 12:33 PM
To: Bracco, Christine
Subject: NYS Vaccination Mandate

I am forwarding an update on the status of the NYS Vaccination Mandate from our Chief HR Officer, Tony Pellicano. I am available all week if you have questions or need any assistance so please don't hesitate to contact me at 631-828-7603. Chris

This is to provide an important update on the status of the NYS COVID-19 vaccination mandate, following my most recent communication on September 23, 2021. There have been some recent, significant developments so it is very important that you review the following information carefully.

As you know, while we awaited further direction from the courts and the NYS Department of Health (DOH), we permitted employees seeking religious exemptions to continue to work subject to PPE and testing requirements. On November 4 and 12, 2021, the U.S. Court of Appeals for the Second Circuit upheld the state mandate without a religious exemption as constitutional and vacated the temporary injunctions that had been issued against the mandate. This means that the Court of Appeals has permitted the DOH to proceed with the mandate without "religious exemptions".

In a letter dated November 15, 2021, the DOH has advised that individuals employed in positions where, if they were infected with COVID-19, they could potentially expose other "covered personnel, patients, or residents to the disease" must receive the first dose of the vaccination by Monday November 22, 2021 in order to be permitted to remain in their positions. The only exceptions allowed are those with religious accommodation requests who also have approved medical exemptions or who can perform their jobs in a way where they will not come into contact with patients, residents or co-workers. We expect there will be few if any positions that satisfy this criteria.

In light of this development, please be advised of the following:

- All employees in "positions such that if they were infected with COVID-19, they could potentially expose other covered personnel, patients or residents to the disease" must have the first dose of the COVID-19 vaccination by Monday, November 22, 2021. This includes all individuals working in hospitals, nursing homes, home care and hospice who have in-person interaction with co-workers, patients or residents as part of their job responsibilities.
- Employees who do not receive the first dose of the vaccination by Monday, November 22, 2021 will be placed on a two week unpaid leave. After that time employees who still have not received the first dose will be terminated and receive their accrued unused vacation time in accordance with our normal policies. However, we will maintain health and welfare benefits until the end of the year. Employees who are terminated due to this action and are fully vaccinated within six months of termination will be eligible to return to work in an available position for which they qualify with no loss of seniority.
- During this time, Catholic Health will consider on an individualized basis whether there are reasonable accommodations available, which might permit employees who have applied for an exemption to the vaccine due to their sincerely held religious beliefs to continue working remotely such that there would be no in-person contact with co-workers, patients or residents. We must advise, however, that most if not all of the positions held by those who have applied for religious accommodations require in-person work in covered facilities such that co-workers, patients or residences could be exposed to COVID-19 should the employee become infected.
- As a result, we strongly encourage our employees who have not yet been vaccinated to consider receiving the first dose of the vaccine by Monday, November 22,

2021 in order to ensure their continued employment. We ask that you notify your manager by Friday, November 19th if you intend to receive the vaccination so that work schedules can be planned accordingly.

As we have stated in earlier communications, as a healthcare system operating in the state of New York we are required to follow the directives issued by the NYS DOH and by the courts. We appreciate your patience and understanding as we continue to navigate through this difficult time. In the final analysis, we owe it to our patients to provide the safest environment possible. We greatly appreciate that 93% of our employees have chosen to take the vaccine and hope that we can continue to all work together to ensure that we meet our promise to the patients we serve.

Tony Pellicano


Chief HR Officer

(516) 705-3716

tony.pellicano@chsli.org<<mailto:tony.pellicano@chsli.org>>

[cid:image002.png@01D7DBAF.266FF470]

12.69 KB  2

 image002.png (5.59 KB)

 N of Timely Response (2).odt (7.10 KB)



Andrew Kosiba
33 Neal Path
South Setauket, NY 11720

Dear Andrew

This will confirm that you have been placed on an unpaid furlough due to your failure to meet the requirements of the NYS mandate for receiving the COVID-19 vaccination. According to the mandate, employees are required to have evidence of at least the first dose of vaccination in order to continue working as of November 22, 2021. In accordance with our previous letter dated November 16th, you will be placed on an unpaid leave for a period of two weeks ending on Monday, December 6th. If you fail to comply with the vaccination requirement by that date, you will be considered to have resigned and your employment will be terminated. In this case your health benefits will be continued through the end of the month and the contribution for December will be deducted from your final pay. If you do not have final pay to cover this cost you will need to self-pay the contribution directly to Baker Tilley in order to be eligible for COBRA benefits. In the event you return to work during the period of the unpaid leave the contributions will be deducted from your next paycheck.

If you decide to get the vaccination and return into an available position with six months of termination you will be eligible for re-employment with no loss of seniority and resume health care coverage on the first of the month following the date of return.

We regret having to take this action and hope that you will reconsider your decision to receive the vaccination and return to Catholic Health. Please direct any questions relating this matter to Christine Bracco at 631-828-7603.

Sincerely,

A handwritten signature in blue ink, appearing to read "C. Bracco", written over a light blue horizontal line.

Christine Bracco
Director of Human Resources
Catholic Home Care/Good Shepherd Hospice

Andrew Kosiba
33 Neal Path
South Setauket, NY 11720
ak764@protonmail.com

Christine Bracco, Human Resources
Catholic Health

christine.bracco@chsl.org

CONFIDENTIAL COMMUNICATION

29 CFR §1630.14(c)(1)

September 20th, 2021.

RE Employment discrimination & retaliation

Hello Christine,

This is a confidential communication that I am requesting be included into my personnel file and I want this and subsequent communications to be kept confidential within human resources. I am documenting acts of retaliation and harassment of which I have been subjected to on the job. I also want to speak confidentially to the **Catholic Health** designated employee or representative for matters involving Title I of the Americans with Disabilities Act and grievances.

Please explain why Catholic Health and its employees are discriminating against me based upon a disability you are regarding me as having? I am invoking my rights under the Americans with Disabilities Act as a qualified individual with a disability.

I am being regarded as having a contagious disease without any individualized assessment and continually being asked for my medical records and to submit to medical examinations and interventions (accommodation or mitigation measures) without any informed consent. It has been extremely difficult to perform my employment duties because of these interruptions and harassment.

Regarding the mitigation measures including but not limited to mask-wearing, vaccines, social distancing, hand-washing and submitting to medical examinations such as the collection of vital statistics (body temperature) or tissue samples (diagnostic testing), I am not required to accept these or any mitigation measures under Title I of the ADA, 29 CFR Part 1630.9(d). If you have some legal authority that overrides this, please provide me with a legal citation.

Title I of the ADA prohibits employers from requiring medical examinations or making disability-related inquiries of employees unless such examination or inquiry is shown to be job-related and consistent with business necessity; see, 42 U.S.C. §12112(d)(4); 29 CFR §1630.14(c)

My questions are:

1. Why do you regard me as having a disability and what records have you made of this?

2. What physician, what medical records, and what complaint made by a physician to a health officer, and "orders of isolation and quarantine" do you rely upon

for diagnosing me as having a contagious disease? Please include all, evidence, court records and records from the individualized assessment used in making this determination or diagnosis as required under Title I of the Americans with Disabilities Act.¹

3. Please identify the statute and regulation imposing your legal duty of care to protect me and others from any contagious disease and the commissioner's pertinent "hazard assessments".

4. Please provide a copy of documentary evidence from the departments of health or labor establishing the existence of a disease that has been isolated by modern scientific standards and documentary evidence proving that such disease is airborne and contagious.

5. Please identify your insurable risk with a copy of your insurance binder showing that you are insured for protecting employees from a contagious disease, and any adverse health consequences they may suffer as a result of your mitigation measures.

6. Regarding the mitigation measures, **a)** why have you refused to include notice that this is under an emergency use authorization, and disclose the risks and benefits of the product, and also advise me of my right to either accept or refuse the product,² and **b)** which of these mitigation measures has the proven efficacy to prevent transmission or infection of the contagious disease for which you regard me as having?

7. How are your requests for my medical information and submitting to medical examinations and interventions necessary for the performance of my employment duties?

8. Why are you able to diagnose me with a deadly disease and impose restrictions and medical interventions without my informed consent, without any physician's oversight or judicial approval, yet I am required to obtain written permission from my physician to exercise my rights to informed consent and medical privacy? We can stipulate that I have never waived any of my rights to medical privacy which includes the right of informed consent as a condition for employment.

Please identify the designated employee responsible for resolving matters concerning the Americans with Disabilities Act and grievances. On the other hand, if you refuse to answer these questions, I will consider the matter closed and we can set it aside and continue with our business without further interruption.

Be advised that if my employment is conditioned upon submitting to your mitigation measures, this constitutes discrimination based upon disability, a violation of state and federal law, and retaliation under the ADA, for which I would have a claim for employment discrimination based upon disability.

Sincerely,

Andrew Kosiba

Please be advised that this communication and all related communications are confidential and must not be disclosed as per the Americans with Disabilities Act explained below.

1 29 CFR 1630.2 et seq.

2 21 USC 360bbb-3

Post Script Memorandum of Law

Title I of the ADA, 42 U.S.C. § 12111, et seq., and its implementing regulation, 29 C.F.R. Part 1630, permits covered employers, such as Catholic Health, to make inquiries into the ability of an employee to perform job-related functions and make inquiries into the nature and severity of the employee's disability, so long as the examination is job-related and consistent with business necessity. 42 U.S.C. §§ 12112(d)(4)(A)–(B); 29 C.F.R. § 1630.14(c). See also Darby v. Childvine, Inc. 964 F.3d 440 (2020) Information obtained as a result of such an examination or inquiry regarding the medical condition or history of any employee must be treated as a confidential medical record. 42 U.S.C. §§ 12112(d)(4)(C), (d)(3)(B); 29 C.F.R. § 1630.14(c)(1).

Confidential medical information may be disclosed in three instances: (1) to inform supervisors or managers regarding necessary restrictions on the work of the employee and necessary accommodations, (2) to medical personnel when emergency treatment is required, and (3) to government officials investigating compliance with this regulation. 42 U.S.C. §§ 12112(d)(4)(C), (d)(3)(B); 29 C.F.R. § 1630.14(c)(1). None of these exceptions apply with regard to my employment with Catholic Health.

Addendum

DEMAND FOR RETRACTION

White House, Department of Justice
and Fox News, CNN, MSN, MSNBC

The White House and Department of Justice, via Jen Psaki, made a false and misleading statement in the White House press briefing dated July 6th, 2021.³

Demand is made the White House and Department of Justice and all news agencies to retract its false statement:

“Section 564(e)(1)(A)(ii)(III) of the Food, Drug, and Cosmetic Act concerns only the provision of information to potential vaccine recipients and does not prohibit public or private entities from imposing vaccination requirements for a vaccine that is subject to an emergency use authorization.”

and the same demand for retraction of the false and misleading title from the article published by Fox News dba Fox TV Digital Team, CNN, MSN, MSNBC and all news agencies that published the following statement in any way:

“Federal law doesn’t prohibit COVID-19 vaccine mandates”

and all commentary supporting this statement, and correct this false statement with the complete opinion which the Department of justice failed to include, which states:

“Whether Section 564 of the Food, Drug and Cosmetic Act Prohibits Entities from Requiring the Use of a Vaccine Subject to an Emergency Use Authorization.”⁴

“We do not address whether other federal, state, or local laws or regulations, such as the Americans with Disabilities Act (“ADA”), might restrict the ability of public or private entities to adopt particular vaccination policies. See, e.g., Equal Employment Opportunity Commission, What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws (updated June 28, 2021), <https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws> (discussing the ADA).”⁵

Demand is made upon the White House, Department of Justice and all news media agencies to retract its false and misleading statements and publish a correction by disclosing its complete and accurate opinion and to correct this in the same manner in which the false and misleading statement was first made (not on the back page of some newspaper).

These false and misleading statements create a danger and public health hazard by encouraging private businesses and government agencies to violate the law. This is the way the government can push its agenda and avoid being challenged, by distributing a policy to literally millions of locations instead of adopting an actual law, it can mislead millions of people into making the wrong conclusions, and in many cases, result in the death or permanent injury of many thousands or millions of people.

3 <https://rumble.com/embed/vhso17/?pub=mt1mb>

4 21 USC §360bbb-3

5 <https://www.justice.gov/sites/default/files/opinions/attachments/2021/07/26/2021-07-06-mand-vax.pdf>

Andrew Kosiba
33 Neal Path
South Setauket, NY 11720
ak764@protonmail.com

David L. Reinman, ADR Coordinator
New York District Office EEOC
33 Whitehall Street, 5th Floor
New York, NY 10004
david.reinman@eeoc.gov

CRTIU Supervisor
New York District Office EEOC
33 Whitehall Street, 5th Floor
New York, NY 10004

Christine Bracco, Human Resources
Catholic Health
110 Bi-County Blvd
Farmingdale, NY 11735
christine.bracco@chsli.org

**For New York District Office EEOC
Charge of Discrimination and Request for Mediation**

Re: Catholic Health
110 Bi-County Blvd
Farmingdale, NY 11735

STATEMENT IN SUPPORT OF COMPLAINT

I am making this complaint against my employer for its discrimination against me based upon disability. The EEOC has the authority and legal duty to investigate this complaint.

My employer regards me as having a disability.

My employer has made a record of such disability.

My employer has failed to conduct any individualized assessment to determine if I am a direct threat to anyone. My employer has failed to engage in any interactive process with me concerning disability rights or resolutions.

Witness List:

Elizabeth Nallan-Potter Elizabeth.Nallan-Potter@chsli.org 631-828-7400

Christine Bracco Christine.Bracco@chsli.org 631-828-7400

Kim Kranz Kim.Kranz@chsli.org 631-828-7400

Tony Pellicano Tony.Pellicano@chsli.org 631-828-7400

Mary Frawley Mary.Frawley@chsli.org 631-828-7400

I have asked to speak confidentially with my employer's designated employee or representative that is responsible for resolving matters involving the Americans with Disabilities Act and grievances thereunder, but my employer refuses to provide me access to such a person.

Instead, my employer has offered various accommodation measures, including, but not limited to mask-wearing, staying six feet away from others, frequent hand-washing, collection, use and storage of my vital statistics, histological samples and biometric data and biometric identifiers without adequate or proper notice, adequate disclosures, adequate data retention security or my informed consent, working in isolation, video-graphic and audio-graphic communications in lieu of face to face communications, working behind clear shielding, and injections of certain types of suspensions which are being called "vaccinations" yet do not prevent infection or transmission of any contagious disease and in fact create more disabilities by altering the normal function of my immune system and other cellular functions. My employer has not merely "offered" such accommodation measures, but threatened me with penalties including those described herein for refusing such accommodations in violation of 29 CFR Part 1630.9(d).

I have thereby informed my employer that I am a qualified individual with a disability that substantially limits my ability to engage in one or more major life activities.

My employer asked me to describe my disability and discuss it with certain employees, even though such disability does not adversely affect my ability to perform the duties of my employment and has done so without any offer or attempt to make such disclosures in confidence or privately.

I have requested information regarding the risks and benefits of my employers accommodation measures and in response, my employer has retaliated against me by humiliating me in front of others, by reprimanding me and has threatened or intimidated or coerced me with the threat of suspension of my pay, reduced hours or pay or the termination of my employment for refusing such accommodation measures instead of providing me with the information I requested so that I could make an informed decision.

I have exercised my right to refuse such accommodation measures and proposed instead that I be permitted to perform my employment duties without harassment, retaliation, coercion, or intimidation as a result of my exercise of such rights, and my employer has prevented and interfered with this occurring.

I have not requested reasonable modifications but only that I be permitted to perform my employment duties without harassment, retaliation, coercion or intimidation.

My employer has instead retaliated against me for exercising my rights under the Americans with Disabilities Act by threatening me with disciplinary measures and penalties for refusing such accommodation measures, including but not limited to suspension or reduction of pay, limiting my access to the premises where I work, segregation, isolation, termination of employment, exclusion from programs or services that would permit me to improve my employment skills or become eligible for advancement, and denied me the possibility for promotion even when I was eligible or would become eligible.

Each day my employer permits and encourages other employees, including my supervisor and managers to harass and intimidate me and ask me for medical, health and other personal information that does not pertain to, or is not necessary for, the performance of my employment duties.

I am thereby being denied equal access to the same programs, activities, benefits, jobs or other opportunities for which I am otherwise qualified, while other employees are not. I am being segregated, excluded and relegated to lesser services by my employer based solely upon disability.

My employer has written and adopted policies that exacerbate my disabilities and create disabilities while also encouraging others to retaliate against me for exercising my rights under the Americans with Disabilities Act.

My employer has failed or refused to fulfill its duty to aid and encourage me in the exercise of my rights which are protected under the Americans with Disabilities Act.

My employer has demonstrated by the actions of its employees and by its own written policies that it intends to continue such violations and failures to comply with the law and violation my rights.

REQUEST FOR MEDIATION

By filing this Charge, I am formally requesting a mediation hearing to resolve these issues. I request that my Charge be entered manually and a hearing be scheduled. I request the CRTIU Supervisor to enter my Charge into the EEOC system personally as I do not find the online portal acceptable or accessible for entering my Charge. I request a written response from the CRTIU Supervisor confirming that my Charge has been filed within 14 business days of receipt of this Notice.

Andrew Kosiba

Enclosure Copies:

- 1.) Notice of Employment Discrimination & Harassment Based on Disability

10/2/21, 8:41 AM

Inbox | ak764@protonmail.com | ProtonMail

Fwd: Harrassment

From: Andrew Kosiba <kosproducts@gmail.com>

To: ak764@protonmail.com <ak764@protonmail.com>

Date: Saturday, October 2nd, 2021 at 6:50 AM

----- Forwarded message -----

From: **Kosiba, Andrew** <Andrew.Kosiba@chsl.org>

Date: Fri, Oct 1, 2021, 8:27 AM

Subject: Harrassment

To: Bracco, Christine <Christine.Bracco@chsl.org>

Cc: ak764@optonline.net <ak764@optonline.net>

Hi Christine,

Thank you for your response. I was not asking for a medical exemption. I am claiming my rights under the ADA since I am being regarded as having an infectious disease and I am asking to be left alone to do my job as I have done faithfully for the last 20 plus years. I want the harassment and discrimination to stop.

By law my employer is required to have an ADA representative. Since you are saying it is you that handles ADA then I want to add 2 incidents to my confidential file.

On Tuesday when entering the building I was told I must take a temperature reading. When I stated "But I already had one and submitted it to my supervisor" and asked "is it still necessary?" I was told yes it is. When I displayed my frustration at this policy, I took the temp reading. As I walked away from the counter I heard "That's one of the ones that will be leaving".

On Thursday I came into the office for a team meeting. During the meeting we were told that if you are vaccinated, they have a sticker to be placed on your badge in order to display the fact that you were vaccinated.

Please enter these incidents into my file. Any further harassment or coercion will be directed to you.

Thank you for your attention.

Sincerely,

Andrew Kosiba

10/19/21, 10:06 AM

Gmail - Confidential file



Andrew Kosiba <kosproducts@gmail.com>

Confidential file

2 messages

Kosiba, Andrew <Andrew.Kosiba@chsli.org>
To: "Bracco, Christine" <Christine.Bracco@chsli.org>
Cc: "ak764@optonline.net" <ak764@optonline.net>

Mon, Oct 18, 2021 at 6:15 PM

Hello Christine,

I wanted to reach out to you so you can add this complaint to my confidential file. I found out that Catholic Health is allowing patients to demand "vaccinated staff only". This is an extremely offensive and discriminatory policy to allow this to happen in the face of a disability. No one should be subjected to this.

It makes me disheartened and sad to find this out. I would hope that the agency would take a stand against this and educate people that this is a discriminatory policy that you cannot abide by.

Thank you for your attention to this matter.

Andrew Kosiba

Bracco, Christine <Christine.Bracco@chsli.org>
To: "Kosiba, Andrew" <Andrew.Kosiba@chsli.org>
Cc: "ak764@optonline.net" <ak764@optonline.net>

Tue, Oct 19, 2021 at 7:59 AM

Good Morning, Andrew.

I will add this to your file.

Take care,

Chris

[Quoted text hidden]

11/5/21, 5:39 PM

(4) Inbox | ak764@protonmail.com | ProtonMail

Fw: UPDATE - New York State COVID-19 Mandate

From: Kosiba, Andrew <Andrew.Kosiba@chsli.org>

To: ak764@protonmail.com <ak764@protonmail.com>

Date: Wednesday, November 3rd, 2021 at 5:13 PM

From: Bracco, Christine

Sent: Wednesday, November 3, 2021 3:35 PM

To: Bracco, Christine

Cc: Verrengia, Michael; Temple, Jennifer; Russo, Adriana L; Kranz, Kim; Alfred, Iyabode (Yabo); Frawley, Mary; Wilson, Christine K. [CHC]; Joachim, Pamela; Sullivan, Roger; McKeever, Maribeth; O'Connor, Carolyn; Winchester, Dionne; Maddock, Kathryn; Donahue, Margaret (Peggy); Silipo, Samantha; Cucci, Patricia; D'Anna, Susan; Koppelman, Syndee; Mirabella, Christine; Savarese, Peter; Schilling, Ann; Lyons-McCreary, Nicole; Sam-Matthews, Suzette; Duggan, Thomas; Farr, Robin A; Wagner, Beth; Nallan-Potter, Elizabeth; Nelson, Christina; Madonia, Ramona; Prisco, Suzanne; Tapley, Jacqueline; Magnani, Lucas; Rowe, Barbara; Page, Kerrienne

Subject: UPDATE - New York State COVID-19 Mandate

I write to you with respect to your pending request for a religious exemption from the New York State COVID-19 vaccine mandate for healthcare workers. As you no doubt are aware, on Friday October 29, 2021, the U.S. Court of Appeals for the 2nd Circuit vacated a lower court preliminary injunction which had blocked New York State from preventing employers from considering requests for religious exemptions from the mandate. In so doing, the Court of Appeals has permitted the New York State COVID-19 vaccine mandate for healthcare workers to proceed without the availability of religious exemptions.

The U.S. Court of Appeals has promised a more detailed opinion, and we have learned that the litigants challenging the vaccine mandate have sought relief from the U.S. Supreme Court. We await further direction in the legal proceedings but must share that the U.S. Supreme Court recently permitted a similar vaccine mandate in the State of Maine to proceed without the availability of religious exemptions.

As we await further direction from the courts, which we expect in the very near term, you will be permitted to continue to work, subject to existing PPE and testing requirements.

Catholic Health Home Care and Good Shepherd Hospice currently perform COVID testing every Monday and Wednesday, between 8am and 1pm, in Farmingdale. Please reach out to Jennifer Temple, Employee Health Nurse, to schedule your bi-weekly COVID test, beginning the week of 11/8/2021.

11/5/21, 5:39 PM

(4) Inbox | ak764@protonmail.com | ProtonMail

Thanks,

Chris

Christine Bracco

Director of Human Resources

Catholic Health Home Care/Good Shepherd Hospice

(631) 828-7603 (Tel)

(631) 566-5656 (Cell)

(631) 828-7610 (Fax)

christine.bracco@chsli.org<<mailto:christine.bracco@chsli.org>>

110 Bi-County Blvd, Suite 114

Farmingdale, NY 11735

11/8/21, 5:07 PM

(6) Inbox | ak764@protonmail.com | ProtonMail

Fw: COVID testing requirement

From: Kosiba, Andrew <Andrew.Kosiba@chsli.org>

To: ak764@protonmail.com <ak764@protonmail.com>

Date: Friday, November 5th, 2021 at 5:13 PM

From: Temple, Jennifer
Sent: Friday, November 5, 2021 11:20 AM
To: Temple, Jennifer
Cc: Bracco, Christine
Subject: COVID testing requirement

Good Morning,

As per previous emails from Human Resources, bi-weekly COVID testing will be required by CH for any employee who is not COVID vaccinated effective week of 11/7/2021, and every other week thereafter. COVID swabbing is performed in Employee Health in Farmingdale on Mondays and Wednesdays between the hours of 8am and 1 pm. You may get tested here or choose to be tested elsewhere. However, if you are tested elsewhere, it is your responsibility to promptly provide me with the results every other week. The test must be PCR, as rapid tests are not acceptable. If you'd like to be tested here in Farmingdale, bi-weekly, you will choose either Monday or Wednesday, and that will be your regular testing day. Please reach out to me via email or practice unite to schedule your day ASAP. If you are already coming to me for testing, please continue to come as usual. If you are being tested elsewhere, or plan to begin testing elsewhere, please let me know where you are being tested. If you have already communicated with me in regards to your testing plans, please disregard this email. As always, feel free to contact me with any questions or concerns.

Thank you,

Jennifer

Jennifer Temple, RN, BSN

Employee Health Nurse

Good Shepherd Hospice & Catholic Home Care

T (631)828-7613

F (631) 828-7610

11/5/21, 5:38 PM

(4) Inbox | ak764@protonmail.com | ProtonMail

Fw: COVID testing requirement

From: Kosiba, Andrew <Andrew.Kosiba@chsli.org>

To: ak764@protonmail.com <ak764@protonmail.com>

Date: Friday, November 5th, 2021 at 5:13 PM

From: Temple, Jennifer
Sent: Friday, November 5, 2021 11:20 AM
To: Temple, Jennifer
Cc: Bracco, Christine
Subject: COVID testing requirement

Good Morning,

As per previous emails from Human Resources, bi-weekly COVID testing will be required by CH for any employee who is not COVID vaccinated effective week of 11/7/2021, and every other week thereafter. COVID swabbing is performed in Employee Health in Farmingdale on Mondays and Wednesdays between the hours of 8am and 1 pm. You may get tested here or choose to be tested elsewhere. However, if you are tested elsewhere, it is your responsibility to promptly provide me with the results every other week. The test must be PCR, as rapid tests are not acceptable. If you'd like to be tested here in Farmingdale, bi-weekly, you will choose either Monday or Wednesday, and that will be your regular testing day. Please reach out to me via email or practice unite to schedule your day ASAP. If you are already coming to me for testing, please continue to come as usual. If you are being tested elsewhere, or plan to begin testing elsewhere, please let me know where you are being tested. If you have already communicated with me in regards to your testing plans, please disregard this email. As always, feel free to contact me with any questions or concerns.

Thank you,

Jennifer

Jennifer Temple, RN, BSN

Employee Health Nurse

Good Shepherd Hospice & Catholic Home Care

T (631)828-7613

F (631) 828-7610

11/11/21, 10:09 PM

(5) Inbox | ak764@protonmail.com | ProtonMail

Fw: COVID Testing

From: Kosiba, Andrew <Andrew.Kosiba@chsli.org>

To: ak764@protonmail.com <ak764@protonmail.com>

Date: Tuesday, November 9th, 2021 at 5:25 PM

From: Temple, Jennifer
Sent: Tuesday, November 9, 2021 8:58 AM
To: Temple, Jennifer
Cc: Bracco, Christine
Subject: COVID Testing

Good Morning ,

As you are aware, effective 11/8/2021, bi-weekly covid swabbing is required for anyone who has a medical or religious exemption . You are receiving this email because you have not provided me information on when and where you will be tested . Testing is available in Farmingdale EHS Mondays and Wednesdays 8a-1pm . if you'd like to begin testing here tomorrow, please let me know ASAP. Otherwise please let me know your testing plans. If you are going to be tested outside of here, it is your responsibility to provide me with the bi-weekly results promptly.

Thank you,

Jennifer Temple, RN, BSN

Employee Health Nurse

Good Shepherd Hospice & Catholic Home Care

T (631)828-7613

F (631) 828-7610

Jennifer.temple@chsli.org

[cid:image001.png@01D7D547.0DDADB00][cid:image005.png@01D7143E.5A5DBEE0]

11/11/21, 10:10 PM

(5) Inbox | ak764@protonmail.com | ProtonMail

Subject: Re: COVID Testing

Good morning Jennifer.

I am aware of the testing that Catholic Health has implemented. I have already spoken with HR regarding these matters ie. mandates, vaccination, testing. These policies are discriminatory. I also feel that they are retaliatory towards those individuals who did not comply. I know there is a list of non-compliant employees. I know that those employees are being treated differently and this is against the law, ie. ADA, Civil Rights Act.

I have logged a complaint with HR. I have also logged a complaint with EEOC as I am regarded as having a disability. This is harassment at this point and I want it to stop.

As you may or may not know, under Emergency Use Authorization (EUA), Informed Consent must be given. I have inquired as to the long term effects of using PCR tests, efficacy, what is done with my personal medical information, how it is stored and have not been able to obtain an answer. Even if these questions are answered, this is a discriminatory policy and I do not consent.

It is also against the law to retaliate against anyone who does not consent to these measures under the EUA.

As I have told HR, I am not asking for any accommodations. I simply wish to be left to perform the job I was hired for over twenty years ago without interruption, a job I take seriously and have done faithfully. If I am ill I will stay home and if need be I will seek medical attention at that point.

I also ask Christine Bracco to add this email correspondence and response to my confidential file as another example of on the job harassment.

Thank you for your attention to this matter.

Sincerely,

Andrew Kosiba

11/11/21, 10:10 PM

(5) Inbox | ak764@protonmail.com | ProtonMail

From: Temple, Jennifer
Sent: Tuesday, November 9, 2021 8:58:18 AM
To: Temple, Jennifer
Cc: Bracco, Christine
Subject: COVID Testing

Good Morning ,

As you are aware, effective 11/8/2021, bi-weekly covid swabbing is required for anyone who has a medical or religious exemption . You are receiving this email because you have not provided me information on when and where you will be tested . Testing is available in Farmingdale EHS Mondays and Wednesdays 8a-1pm . if you'd like to begin testing here tomorrow, please let me know ASAP. Otherwise please let me know your testing plans. If you are going to be tested outside of here, it is your responsibility to provide me with the bi-weekly results promptly.

Thank you,

Jennifer Temple, RN, BSN

Employee Health Nurse

Good Shepherd Hospice & Catholic Home Care


T (631)828-7613


F (631) 828-7610

Jennifer.temple@chsli.org<<mailto:Jennifer.temple@chsli.org>>

[cid:image001.png@01D7D652.82BAEDF0][cid:image005.png@01D7143E.5A5DBEE0]

606.51 KB  3

 image001.png (6.06 KB)

 image002.png (7.27 KB)

 COVID-19 Vaccinations Final 9121.pdf (593.18 KB)

11/11/21, 10:10 PM

(5) Inbox | ak764@protonmail.com | ProtonMail

Fw: COVID Testing

From: Kosiba, Andrew <Andrew.Kosiba@chsli.org>

To: ak764@protonmail.com <ak764@protonmail.com>

Date: Thursday, November 11th, 2021 at 7:53 AM

From: Bracco, Christine

Sent: Wednesday, November 10, 2021 4:59 PM

To: Kosiba, Andrew; Temple, Jennifer

Subject: RE: COVID Testing

Hi Andrew,

In accordance with the Catholic Health Policy, COVID-19 Vaccinations effective September 27, 2021, employees not vaccinated must adhere to bi-weekly COVID-19 testing. Attached is a copy of the policy for your review.

As an employee with a pending request for an accommodation which remains under review, you will be required to have negative COVID-19 test results on a bi-weekly basis in order to continue reporting to work. COVID testing may be conducted in the Employee Health department or you may choose an outside testing site that is more convenient for you as long as the test results are submitted within five (5) days of the test date.

Please work with Jen to ensure the testing is completed within the time frame specified.

Thank you for your cooperation.

Take care,

Chris

From: Kosiba, Andrew <Andrew.Kosiba@chsli.org>

Sent: Wednesday, November 10, 2021 4:01 PM

To: Temple, Jennifer <Jennifer.Temple@chsli.org>

Cc: Bracco, Christine <Christine.Bracco@chsli.org>



Andrew Kosiba
33 Neal Path
South Setauket, NY 11720

Dear Andrew

This will confirm that you have been placed on an unpaid furlough due to your failure to meet the requirements of the NYS mandate for receiving the COVID-19 vaccination. According to the mandate, employees are required to have evidence of at least the first dose of vaccination in order to continue working as of November 22, 2021. In accordance with our previous letter dated November 16th, you will be placed on an unpaid leave for a period of two weeks ending on Monday, December 6th. If you fail to comply with the vaccination requirement by that date, you will be considered to have resigned and your employment will be terminated. In this case your health benefits will be continued through the end of the month and the contribution for December will be deducted from your final pay. If you do not have final pay to cover this cost you will need to self-pay the contribution directly to Baker Tilley in order to be eligible for COBRA benefits. In the event you return to work during the period of the unpaid leave the contributions will be deducted from your next paycheck.

If you decide to get the vaccination and return into an available position with six months of termination you will be eligible for re-employment with no loss of seniority and resume health care coverage on the first of the month following the date of return.

We regret having to take this action and hope that you will reconsider your decision to receive the vaccination and return to Catholic Health. Please direct any questions relating this matter to Christine Bracco at 631-828-7603.

Sincerely,

A handwritten signature in dark ink, appearing to read "Christine Bracco", written over a light blue horizontal line.

Christine Bracco
Director of Human Resources
Catholic Home Care/Good Shepherd Hospice

11/29/21, 2:19 PM

(1) Sent | ak764@protonmail.com | ProtonMail

Work

From: Andrew.Kosiba@chsli.org <Andrew.Kosiba@chsli.org>

To: Christine.Bracco@chsli.org <Christine.Bracco@chsli.org>
Nallan-Potter, Elizabeth <Elizabeth.Nallan-Potter@chsli.org>

CC: ak764@protonmail.com <ak764@protonmail.com>

Date: Monday, November 29th, 2021 at 8:08 AM

Hello Christine.

I am writing this email after I was on a scheduled vacation for the past week. This is in response to the letter I received about my being placed on "unpaid leave" due to not receiving the shot.

I want to be very clear. I have no intention of resigning my position as physical therapist. This was never made as a condition of my employment that I was hired for, to be involuntarily injected with a shot under experimental use authorization. I have the right to refuse ANY experimental procedures which this falls under.

I am ready, able and willing to return to work. You have no evidence that proves that I am a threat to anyone's health over anyone else that is employed by Catholic Health, including your "vaccinated" staff. According to the CDC and the WHO, those individuals can be infected and spread the illness called Covid-19. Yet, I, and others like me who know their rights, are being disciplined and under threat to being fired.

If it is your intention to fire me, I will need a letter stating that I am fired for this reason and signed by you.

I feel this is an outrageous stance that Catholic Health and you have taken. Saying that your "hands are tied" is not an excuse. Instead of fighting the unlawfulness of these "mandates" with your legal team, you have chosen to discipline your faithful employees. No one should have to face this kind of tyranny.

Sincerely,

Andrew Kosiba, PT, DPT

Return to work

From: Andrew.Kosiba@chsli.org <Andrew.Kosiba@chsli.org>
To: Christine.Bracco@chsli.org <Christine.Bracco@chsli.org>
Nallan-Potter, Elizabeth <Elizabeth.Nallan-Potter@chsli.org>
CC: ak764@protonmail.com <ak764@protonmail.com>
Date: Tuesday, November 30th, 2021 at 9:47 AM

Hello Christine,

Today is Tuesday, 11/30/2021. I wanted to send this email to emphasize that I am healthy and I am ready, willing and able to return to work.

Regards,

Andrew Kosiba

Work

From: Andrew.Kosiba@chsli.org <Andrew.Kosiba@chsli.org>
To: Christine.Bracco@chsli.org <Christine.Bracco@chsli.org>
Nallan-Potter, Elizabeth <Elizabeth.Nallan-Potter@chsli.org>
CC: ak764@protonmail.com <ak764@protonmail.com>
Date: Wednesday, December 1st, 2021 at 9:56 AM

Hello Christine.

As you may or may not know, yesterday, a federal judge has ruled in favor of healthcare workers and has deemed the "mandate" put forth by the Biden administration to be unconstitutional nationwide.

Today is Wednesday, December 1, 2021. I wanted again to reiterate that I am healthy and I am ready, willing and able to work. I am no more of a threat to anyone's health than anyone else who is currently working.

Sincerely,

Andrew Kosiba, PT, DPT

Work

From: Andrew.Kosiba@chsli.org <Andrew.Kosiba@chsli.org>
To: Christine.Bracco@chsli.org <Christine.Bracco@chsli.org>
Nallan-Potter, Elizabeth <Elizabeth.Nallan-Potter@chsli.org>
CC: ak764@protonmail.com <ak764@protonmail.com>
Date: Thursday, December 2nd, 2021 at 8:46 AM

Hello Christine.

Today is 12/2/2021. I wanted to again state that I am healthy, willing, ready and able to work.

Regards,

Andrew Kosiba, PT, DPT

Fw: Work

From: Andrew.Kosiba@chsli.org <Andrew.Kosiba@chsli.org>

To: ak764@protonmail.com <ak764@protonmail.com>

Date: Friday, December 3rd, 2021 at 8:29 AM

From: Bracco, Christine

Sent: Thursday, December 2, 2021 10:05 AM

To: Kosiba, Andrew; Nallan-Potter, Elizabeth

Subject: RE: Work

Hi Andrew,

This is in response to your inquiry about the recent court decision in Louisiana, where a federal district judge issued a temporary injunction against the implementation of the vaccine mandate for healthcare workers issued by the Centers for Medicare and Medicaid Services (CMS). That ruling only applies to the CMS vaccine mandate and was premised on a determination that CMS, as an administrative agency, lacked the authority to issue a vaccine mandate. It has nothing at all to do with the New York State vaccine mandate for healthcare workers which was upheld by the U.S. Court of Appeals for the 2nd Circuit, which is the highest federal court with jurisdiction over New York (apart from the U.S. Supreme Court). The New York State vaccine mandate for healthcare workers remains in effect and we continue to be subject to it as a health care entity regulated by the NYS Department of Health.

Chris

From: Kosiba, Andrew <Andrew.Kosiba@chsli.org>

Sent: Wednesday, December 1, 2021 9:57 AM

To: Bracco, Christine <Christine.Bracco@chsli.org>; Nallan-Potter, Elizabeth <Elizabeth.Nallan-Potter@chsli.org>

Cc: ak764@protonmail.com

Subject: Work

Hello Christine.

As you may or may not know, yesterday, a federal judge has ruled in favor of healthcare workers and has deemed the "mandate" put forth by the Biden administration to be unconstitutional nationwide.

Today is Wednesday, December 1, 2021. I wanted again to reiterate that I am healthy and I am ready, willing and able to work. I am no more of a threat to anyone's health than anyone else who is currently working.

Sincerely,

Andrew Kosiba, PT, DPT

Fw: Work

From: Andrew.Kosiba@chsli.org <Andrew.Kosiba@chsli.org>

To: ak764@protonmail.com <ak764@protonmail.com>

Date: Friday, December 3rd, 2021 at 8:41 AM

From: Kosiba, Andrew
Sent: Friday, December 3, 2021 8:41 AM
To: Bracco, Christine; Nallan-Potter, Elizabeth
Subject: Re: Work

Hello Christine,

The judge who ruled in the case in Louisiana ruled that the mandate is unconstitutional. If it is unconstitutional then that means across the board against the constitution. I feel that Catholic Health is entering into dangerous territory under the color of law. Also, the behavior of Catholic Health and it's employees is unlawful against the ADA and Civil Rights Act which was my point from the beginning. Many healthcare entities in many states are backing away from the mandates already. I really feel that Catholic Health should also reconsider.

I also reiterate that today is 12/3/2021 and I am healthy, able, willing and ready to work. Your excuse that I would be a danger to anyone I treat as a patient any more than any "vaccinated" employee is erroneous and false as per the studies that show that "vaccinated" people can also get infected and spread the "virus".

Sincerely,

Andrew Kosiba, PT, DPT

From: Bracco, Christine
Sent: Thursday, December 2, 2021 10:05 AM
To: Kosiba, Andrew; Nallan-Potter, Elizabeth
Subject: RE: Work

Hi Andrew,

This is in response to your inquiry about the recent court decision in Louisiana, where a

federal district judge issued a temporary injunction against the implementation of the vaccine mandate for healthcare workers issued by the Centers for Medicare and Medicaid Services (CMS). That ruling only applies to the CMS vaccine mandate and was premised on a determination that CMS, as an administrative agency, lacked the authority to issue a vaccine mandate. It has nothing at all to do with the New York State vaccine mandate for healthcare workers which was upheld by the U.S. Court of Appeals for the 2nd Circuit, which is the highest federal court with jurisdiction over New York (apart from the U.S. Supreme Court). The New York State vaccine mandate for healthcare workers remains in effect and we continue to be subject to it as a health care entity regulated by the NYS Department of Health.

Chris

From: Kosiba, Andrew <Andrew.Kosiba@chsli.org>
Sent: Wednesday, December 1, 2021 9:57 AM
To: Bracco, Christine <Christine.Bracco@chsli.org>; Nallan-Potter, Elizabeth <Elizabeth.Nallan-Potter@chsli.org>
Cc: ak764@protonmail.com
Subject: Work

Hello Christine.

As you may or may not know, yesterday, a federal judge has ruled in favor of healthcare workers and has deemed the "mandate" put forth by the Biden administration to be unconstitutional nationwide.

Today is Wednesday, December 1, 2021. I wanted again to reiterate that I am healthy and I am ready, willing and able to work. I am no more of a threat to anyone's health than anyone else who is currently working.

Sincerely,

Andrew Kosiba, PT, DPT

Re: Religious Exemption

From: Andrew.Kosiba@chsli.org <Andrew.Kosiba@chsli.org>
To: Christine.Bracco@chsli.org <Christine.Bracco@chsli.org>
CC: ak764@protonmail.com <ak764@protonmail.com>
Date: Friday, December 3rd, 2021 at 8:50 AM

Hello Christine,

In response to this email, I want to reiterate that I pose no more danger to any of my patients than any "vaccinated" employee as per the science. They can become infected and they can spread the infection as you assume that I would.

I am also reiterating that I am not resigning my position and if you intend to fire me over this then I want a signed letter stating this.

Sincerely,

Andrew Kosiba, PT, DPT

From: Bracco, Christine
Sent: Thursday, December 2, 2021 9:10 AM
To: Kosiba, Andrew
Subject: Religious Exemption

Hi Andrew,

I write with respect to your request for a religious exemption from the NYS Covid-19 vaccine mandate for healthcare workers. As we previously communicated, the NYS Department of Health (DOH) and the U.S. Court of Appeals for the Second Circuit have directed that religious exemptions from the vaccine mandate are not available.

While religious exemptions from the NYS vaccine mandate are not available, the DOH and the Court of Appeals have authorized religious accommodations in very limited circumstances. In particular, the DOH and the U.S. Court of Appeals have stated that unvaccinated employees may continue to work for "covered entities" such as Catholic Health Home Care only where they can perform their jobs in a way where if they were to contract COVID-19, they could not potentially expose covered personnel, patients or residents to COVID-19. In other words, the position must be one in which an unvaccinated employee will not come into contact with patients, residents or co-workers of Catholic Health Home Care. We simply are not permitted to allow unvaccinated employees in covered positions to continue

to work even with appropriate PPE and subject to COVID-19 testing.

We have carefully considered your religious accommodation request in accordance with these judicial and regulatory directives. We have assumed for purposes of this review only that your accommodation request is premised on a sincerely held religious belief. Having made that assumption, we must next determine whether you are able to perform your work in a manner where you will not come into contact with patients, such as through remote work, so that if you were to contract COVID-19, you could not potentially expose patients, co-workers or residents to COVID-19.

As you know, your position as Physical Therapist requires that you work in-person in patient homes and that you have frequent, direct contact with patients. Having you perform your work duties in an isolated or remote manner simply is not feasible and would pose an undue hardship for Catholic Home Care as it carries out its important health care work. Similarly, as a regulated health care entity, we must follow the directives of the DOH and the U.S. Court of Appeals. Not following those directives would pose an undue hardship for Catholic Health Home Care as we would be subject to, among other things, enforcement actions, penalties and even the potential loss of our ability to continue operations.

We regret to inform you of this decision. We hope that you will consider receiving the COVID-19 vaccination during your unpaid leave of absence period so that you can continue in employment with us and return to work. Please feel free to contact me with any questions.

Chris

Christine Bracco

Director of Human Resources

Catholic Health Home Care/Good Shepherd Hospice

(631) 828-7603 (Tel)

(631) 566-5656 (Cell)

(631) 828-7610 (Fax)

christine.bracco@chsli.org<<mailto:christine.bracco@chsli.org>>

110 Bi-County Blvd, Suite 114

Farmingdale, NY 11735

EXHIBIT B

Guidance for Industry and FDA

Classification of Products as Drugs and Devices & Additional Product Classification Issues: Guidance for Industry and FDA Staff

FINAL GUIDANCE

Additional copies are available from:

*Office of Combination Products
Food and Drug Administration
WO32, Hub/Mail Room #5129
10903 New Hampshire Avenue
Silver Spring, MD 20993
(Tel) 301-796-8930
(Fax) 301-847-8619*

<http://www.fda.gov/CombinationProducts/default.htm>.

For questions regarding this document contact the Office of Combination Products at 301-796-8930 or combination@fda.gov.

**U.S. Department of Health and Human Services
Food and Drug Administration
Office of Combination Products
Office of Special Medical Programs
Office of the Commissioner**

September 2017

Contains Nonbinding Recommendations

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Classification of Products as Drugs and Devices & Additional Product Classification Issues: Guidance for Industry and FDA Staff¹

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed on the title page of this guidance.

I. INTRODUCTION¹

FDA regularly receives questions from medical product sponsors concerning the classification of their products.² We believe that efficient, effective regulation is facilitated by providing guidance on issues frequently raised in relation to Requests for Designation (RFDs) and other classification activities. In addition, providing as much clarity and predictability as possible with respect to product classifications should enable informed planning for product development. Accordingly, we have prepared this guidance to make the Agency's current thinking concerning certain product classification issues more readily and widely available.

While issues have arisen relating to whether a product should be classified as a drug, device, biological product, or combination product, most of these issues have related to whether a product should be classified as either a drug or a device.³ Accordingly, this guidance focuses particularly on cases in which a product⁴ may be classified as a drug or device.⁵ This guidance also addresses additional issues relating to product classification, including how to obtain classification determinations from FDA for medical products.

This guidance is organized into two substantive sections.

¹ This guidance has been prepared by the Office of Combination Products in consultation with the Center for Biologics Evaluation and Research, the Center for Devices and Radiological Health, and the Center for Drug Evaluation and Research.

² Please note that "classification" as used in this guidance refers to a product's designation as a drug, device, biological product, or combination product. This is distinct from the use of the term "classification" in reference to the class (Class I, II, or III) of a device as described in section 513(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

³ This guidance addresses the definitions for the terms drug, device, and biological product in section III. The term "combination product" is defined in 21 CFR 3.2(e). For further information regarding the definition for the term combination product and the regulation of combination products, please visit the webpage for the Office of Combination Products at www.fda.gov/CombinationProducts/default.htm.

⁴ The guidance's discussion of the classification of products is also relevant to classification of the constituent parts of a combination product.

⁵ This guidance focuses on classification of products for human use. Distinct considerations may apply in determining how to classify a product intended for use in animals.

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Section II offers guidance on the RFD process for obtaining a formal determination of a product's classification.

Section III presents general concepts regarding FDA's decision-making process for classification determinations and addresses issues that may arise in determining whether products should be classified as drugs or devices.⁶

The Agency recommends that sponsors contact the Office of Combination Products (OCP) to confirm the classification of any products they may wish to market if the appropriate classification is unclear or in dispute. Section IV provides contact information for OCP and responses to frequently asked questions.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word "should" in Agency guidances means that something is suggested or recommended, but not required.

II. WHAT IS THE PROCESS FOR OBTAINING A FORMAL CLASSIFICATION DETERMINATION FOR A PRODUCT?

If the classification of a product as a drug, device, biological product, or combination product is unclear or in dispute, a sponsor can submit an RFD to OCP in accordance with Part 3 of Title 21 of the Code of Federal Regulations (21 CFR Part 3) to obtain a formal classification determination for the product, as provided for under section 563 of the FD&C Act (21 USC 360bbb-2). Any RFD determined to be incomplete will be returned to the sponsor with a request for the missing information.⁷ 21 CFR 3.8(a). Once OCP determines the RFD is complete for filing, the Agency reviews the RFD.

The sponsor recommends a classification in the RFD, and should explain the basis for the recommendation. While the sponsor should justify why it believes the product meets the recommended classification, we generally consider both the information provided in the RFD and other information available to the Agency at that time in making our designation.

Generally, OCP will respond to the sponsor in writing within sixty days of the RFD filing, identifying the classification of the product as a drug, device, biological product, or

⁶ This section generally focuses on approaches for determining whether a product should be classified as a drug or a device, based on application of the statutory definitions for these terms under sections 201(g) and 201(h) of the FD&C Act (21 USC 321(g) and (h)), respectively. Please note that this document does not focus on the classification of products as biological products regulated under section 351(i) of the Public Health Service Act (PHS Act) (42 USC 262(i)). It also does not address under what circumstances certain human cells, tissues, or cellular or tissue-based products (HCT/Ps), as defined in 21 CFR Part 1271, are regulated solely under section 361 of the PHS Act. For guidance concerning HCT/Ps, please visit <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/>.

⁷ See 21 CFR 3.7 for content requirements for RFDs.

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combination product. If the Agency does not provide a written response within sixty days, the sponsor's recommendation respecting the classification of the product is considered to be the final determination. 21 USC 360bbb-2(b) and (c).

RFD determinations pertain only to the product as described in the designation letter, including its proposed use(s) or indication(s) for use. The Agency may modify a determination made under section 563 regarding the classification of a product or the component of FDA that will regulate the product either with the written consent of the sponsor or for public health reasons based on scientific evidence. 21 USC 360bbb-2(b) and (c).⁸

A new determination may be appropriate if there is a change in, for example, a proposed indication for use or in a component of the product, or if the sponsor or Agency becomes aware of additional information that reveals that the means by which the product achieves its primary intended purposes differ from what was originally described in the RFD. For example, if a sponsor wished to change the indication for a product and that new indication would be achieved through a different mechanism than the original indication, a different classification for the new indication might be appropriate.

Please contact OCP if you have questions regarding whether to submit an RFD, what information to provide, or issues to address in an RFD to ensure its completeness and clarity.⁹

III. WHAT DOES FDA CONSIDER IN DETERMINING WHETHER TO CLASSIFY A PRODUCT AS A DRUG OR DEVICE?

FDA's determination of whether to classify a product as a drug or device is based on statutory definitions, as set forth in sections 201(g) and 201(h) of the FD&C Act, respectively. We apply these definitions to products, relying on the scientific data that are available to FDA at the time of the classification determination concerning the product for its proposed use(s)/indication(s).¹⁰

⁸ The sponsor may request reconsideration of the decision if its classification recommendation is not adopted by the Agency. See 21 CFR 3.8, 10.75. If the sponsor develops or becomes aware of new information that may affect the product's classification, the sponsor may also submit a new RFD seeking a new determination.

⁹ More detailed information on the RFD process is provided in OCP's guidance *How to Write a Request for Designation (RFD)*, available at <http://www.fda.gov/RegulatoryInformation/Guidances/ucm126053.htm>. A pre-RFD process is available if a sponsor wishes to obtain a preliminary, non-binding classification determination or to engage in preliminary classification discussions with the Agency before filing a formal RFD. The RFD and pre-RFD processes are also available to sponsors to clarify the Center assignment for medical products, though this issue is beyond the scope of this guidance. More information about the pre-RFD process is available at <https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM534898.pdf>.

¹⁰ If a product type has been classified by regulation, FDA would generally classify the product (including as a constituent part of a combination product) in accordance with the regulation, if the product (or constituent part) falls within the scope of that regulation. If the Agency concludes that it may be appropriate to propose changing a classification established by regulation, FDA would initiate notice and comment rulemaking to do so.¹¹ The device definition also includes a second exclusionary clause stating that a device "is not dependent upon being metabolized for the achievement of its primary intended purposes." This clause has not been at issue frequently in classification determinations. Accordingly, we do not offer guidance on its construction here. If sponsors have questions regarding the Agency's interpretation of this clause, they may contact OCP.

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Medical product classification determinations often focus substantially on whether a product that meets the definition of drug also meets the statutory definition of device. This section presents the drug and device definitions and discusses how the Agency addresses certain issues that arise when determining whether a product should be classified as a drug or device.

A. Statutory Definitions

1. Drug

Section 201(g) of the FD&C Act (21 USC 321(g)) provides that the term "drug" means:

(A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C). . . .

2. Device

Section 201(h) of the FD&C Act (21 USC 321(h)) provides that the term "device" means:

an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is--

- (1) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- (3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

B. Certain key provisions of the definition of device

Conceptually, all FDA-regulated medical products meet the definition of "drug" under section 201(g) of the FD&C Act, due to the broader scope of the drug definition. For a medical product also to meet the more restrictive device definition under section 201(h) of the FD&C Act, it must (i) be "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article," and (ii) "*not* achieve its primary intended purposes through *chemical action* within or on the body of man or other animals" and (iii) "*not* [be] dependent upon being *metabolized* for the achievement of its primary intended purposes" (emphasis added).

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The sponsor presumably has the most complete information relevant to how its proposed product achieves its primary intended purpose(s). Sponsors seeking a classification determination should present all available data and other information potentially relevant to that determination (without regard to whether the data or information supports the sponsor's preferred outcome). For example, for a sponsor seeking to classify its proposed product as a device, those data should demonstrate that its product meets the definition of a device.

At the classification stage, sponsors would not be expected to have gathered sufficient data to demonstrate that their proposed product meets the applicable marketing authorization standard (e.g., data demonstrating effectiveness). Therefore, the focus of FDA's classification analysis is on how the product would be expected to achieve its primary intended purposes, assuming it is capable of achieving its primary intended purposes at all. FDA will use its best scientific judgment to evaluate all available information relevant to the classification determination, including information submitted by the sponsor or available in the literature.

The following discussion presents the Agency's current thinking on certain issues that arise with respect to the statutory definition of device.

1. "Similar or related article" in the definition of device

The first clause of the device definition provides that the term "means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or *other similar or related article . . .*" (emphasis added). The issue of whether a product may be considered a "similar or related article" under this clause can arise, for example, with regard to products in liquid, semi-liquid, gel, gas, or powder form. In some cases, such products are appropriately considered "similar or related articles," and may be classified as devices, so long as they also satisfy the remainder of the device definition under section 201(h) of the FD&C Act, including the chemical action exclusion discussed in section III.B.3 below. This could be the case, for example, for gels or powders put on the skin as a barrier, gases used as space fillers, or liquids used to clean either surgical instruments or contact lenses.

2. "Primary intended purposes" in the definition of device

Most often, in determining whether a product meets the device definition, questions arise concerning the exclusionary clause of the definition, which provides that a device is a product "which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals . . ."¹¹ A product that has chemical action could be a device if it does not achieve its primary intended purposes through that chemical action.

¹¹ The device definition also includes a second exclusionary clause stating that a device "is not dependent upon being metabolized for the achievement of its primary intended purposes." This clause has not been at issue frequently in classification determinations. Accordingly, we do not offer guidance on its construction here. If sponsors have questions regarding the Agency's interpretation of this clause, they may contact OCP.

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For example, if the primary intended purpose of a hip joint replacement implant is to restore movement, and the implant also elicits a foreign body response through chemical action, that response would not be considered a primary intended purpose of the implant. Accordingly, such an implant could be classified as a device despite the chemical action, because such action does not achieve the product's primary intended purpose. Similarly, if the primary intended purpose of an absorbable suture is to rejoin tissue, and the suture is also designed to be resorbed by the body through a combination of chemical action and metabolic activities, such resorption would not be considered a primary intended purpose of the product. Accordingly, such an absorbable suture could be classified as a device despite the chemical action and metabolic activity, because such action or activity does not achieve the product's primary intended purpose.

3. “Chemical action” in the definition of device

FDA frequently receives questions from product sponsors concerning the Agency's interpretation of the term “chemical action.” This term must be read in the context of the statutory definition of “device” as a whole. The determination of whether a product meets the device definition does not depend solely on whether the product exhibits “chemical action.” In particular, as explained in section III.B.2 and 4, a product that exhibits chemical action will still meet the device definition if the product “does not achieve its primary intended purposes through” that chemical action “within or on the body,” and otherwise satisfies the device definition.

Under the Agency's interpretation of the device definition, a product exhibits “chemical action” if it interacts at the molecular level with bodily components (e.g., cells or tissues) to mediate (including promoting or inhibiting) a bodily response, or with foreign entities (e.g., organisms or chemicals) so as to alter that entity's interaction with the body.¹² We note that this type of interaction is consistent with the term “pharmacological action” as that term is generally understood in the medical field. Accordingly, we have used “pharmacological action” as a shorthand throughout the rest of this guidance for ease of explication and recognition. The examples presented in section III.B.5 offer illustration of FDA's interpretation of chemical action.

4. “Within or on the body” in the definition of device

Because a device “does not achieve its primary intended purposes through chemical action *within or on the body* of man or other animals” (emphasis added), a product can be a device even if it achieves its primary intended purposes through chemical action, so long as the chemical action does not occur “within or on the body” (and the product meets the other elements of the definition of device under section 201(h)).

Whether chemical action is occurring “within or on the body” is generally a straightforward matter. If the chemical action is occurring inside the body or on the surface of the body, it is within or on the body. For example, the chemical action of an orally ingested pill

¹² For purposes of this interpretation, an interaction at the molecular level occurs through either chemical reaction (i.e., formation or breaking of covalent or ionic bonds), intermolecular forces (e.g., electrostatic interactions), or both. The mere exchange of non-chemical energy (e.g., electromagnetic or thermal energy) between a product and the body would not constitute “chemical action.”

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or tablet of a decongestant would be “within the body,” and the chemical action of a spray or cream for treatment of dermatitis when applied to the skin would be “on the body.” Similarly, it is generally a straightforward matter to determine that chemical action is not occurring within or on the body. For example, the chemical action of an antimicrobial agent used to clean a surgical instrument before that instrument is used is not occurring within or on the body.

However, the Agency has on occasion considered some situations in which it may be less clear whether chemical action is occurring within or on the body. For example, we have determined that chemical action occurring solely within an extracorporeal device, specifically a kidney hemodialysis machine, is not occurring within or on the body. Similarly, we have determined that the chemical action of a transport solution to preserve a donor organ for transplantation while in an organ transport container is not occurring within or on the body.

5. Illustrative Examples

The following examples further illustrate the application of some of the key provisions of the device definition discussed above. Table 1 contains some examples of medical products that achieve their primary intended purposes through chemical action within or on the body. Table 2 contains some examples of medical products that do not achieve their primary intended purposes through chemical action within or on the body.

Table 1: Examples of Medical Products that Achieve Their Primary Intended Purposes through Chemical Action within or on the Body

Product	Description
Aspirin	Aspirin is used for pain relief. Acetylsalicylic acid (aspirin) contains an acetyl group that has the ability to covalently bind to a serine residue of a cyclooxygenase enzyme (COX-1 or COX-2). This is considered pharmacological action because it inactivates the enzyme and thereby inhibits the synthesis of prostaglandin and thromboxanes, which suppresses the body’s inflammatory response for pain relief.
Beta Blockers	Beta blockers are used to reduce blood pressure. Cells contain beta receptors that can be stimulated by neurotransmitters such as adrenaline/epinephrine. Beta blockers, like propranolol, bind beta receptors (b1 and b2) and exhibit pharmacological action by inhibiting the activation of the signaling cascade. This blockage causes cardiac cells to reduce the strength of cardiac contractions and heart rate.
Magnesium Sulfate	Magnesium sulfate is used as replacement therapy for magnesium deficiency. It acts as a catalyst in enzymatic reactions (a molecular-level interaction). While the chemical or atomic structure of magnesium sulfate is not altered, its participation in enzymatic reactions is considered a pharmacological action because it impacts various cellular and molecular processes.

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Polymyxin B Sulfate	Polymyxin B sulfate is an antibiotic that is used to treat bacterial infection. It is composed of a cationic protein surfactant that has fatty acid functional groups. Polymyxin B sulfate acts through intermolecular forces, by binding to components of the bacterial membrane (i.e., the membrane of the foreign entity) and by association/fusion of the fatty acid portion of the molecule with the lipid bilayer via hydrophobic interactions. This binding is a pharmacological action because it disrupts the integrity of the bacterial membrane, which causes organism death, thereby treating the bacterial infection.
Hydroxocobalamin	Hydroxocobalamin is used as an antidote to cyanide poisoning. The cobalt moiety of hydroxocobalamin exhibits pharmacological action because it chemically reacts with cyanide, a toxic chemical agent, to form cyanocobalamin, a non-toxic compound, and the ability of hydroxocobalamin to interact with cyanide facilitates the removal of the toxic agent in order to inhibit the toxic effects of cyanide on the body.

Table 2: Examples of Medical Products That Do Not Achieve Their Primary Intended Purposes through Chemical Action within or on the Body

Product	Description
Abdominal Adhesion Barrier	Inert, biodegradable synthetic polymers can be used to reduce post-operative adhesions with tissues and organs within the abdominal cavity. An implanted physical barrier sheet composed of such polymers would act to reduce adhesion through physical separation of tissue and not through pharmacological action on the surrounding tissue.
Polymethylmethacrylate (PMMA)	PMMA is an acrylate polymer that is used as a temporary bone spacer. PMMA is built from methyl methacrylate monomer units, which undergo free radical polymerization in the presence of an initiator compound. The molecules that are part of the polymerization process interact with each other to create a solid mass to fill a bone void physically. The process does not require an interaction between the PMMA and the bone at the molecular level and, therefore is not considered chemical action within or on the body.
Topical Surgical Adhesive	Cyanoacrylate is an acrylic resin that is used to approximate skin tissue as an adjunct to a wound closure product. The resin undergoes anionic polymerization in the presence of water. The chemical reaction that occurs between the resin and ions in the water allows it to form into long polymer chains. This type of adhesive can bond to a cut/incision, creating a physically-intact film to aid in keeping skin edges together. While the product binds to tissue, it does not exhibit pharmacological action because that binding does not mediate a bodily response.

Contains Nonbinding Recommendations

Gold Nanoparticles	Nanoparticles composed of gold can be used to treat cancer. When gold nanoparticles are injected into a tumor site and exposed to electromagnetic energy, they absorb the electromagnetic energy and convert it to thermal energy, and this heat is transferred to the surrounding cells or tissue. The heat transfer, as opposed to a binding interaction with the nanoparticle, causes the cancer cells to die. Therefore, this effect is not achieved through chemical action.
Cryosurgery for Wart Removal	Cryogen (liquid gas), such as nitrogen or dimethyl ether, is used to treat common and plantar warts. The liquid gas is extremely cold and freezes the wart, resulting in damage to the topmost layer of cells. A physiological effect (i.e., cell death) results from heat transfer, not from a binding interaction with the gas. Therefore, the freezing is not considered chemical action.
Dental Amalgam	A resin that fills a cavity in a tooth as part of the treatment of dental caries may bind to the tooth via covalent bonding, or rely in part on intermolecular forces to change from liquid or paste to solid form. However, this binding and/or state change does not mediate a bodily response, but rather produces a solid mass, to fill the cavity. Therefore, it would not be considered chemical action.
Respirator Mask with Antimicrobial Filter	An antimicrobial product impregnated into a filter on a respirator mask to kill microbes that the user might otherwise inhale would exhibit pharmacological action. However, while the mask is in contact with the user's face, the filter is not. So, the chemical action occurring on the filter is not occurring within or on the body.

C. How is a product classified if it meets the definition for drug (or for both drug and device) and also meets the definition for biological product?

As explained in section III.B, products that meet the device definition in 201(h) of the FD&C Act also meet the drug definition in 201(g) of the FD&C Act. In addition, products that meet the drug definition, or both the drug and device definitions, may also meet the definition of biological product under section 351(i) of the PHS Act (42 USC 262(i)).

Section 351(i) provides that:

The term “biological product” means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide),¹³ or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

¹³ For guidance on FDA’s interpretation of the category “protein (except any chemically synthesized polypeptide)” see *Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009*, at Q.II.1 (April 2015), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM444661.pdf>.

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Products that meet the drug definition and that also meet the definition of biological product are classified as biological products, and are generally subject to licensure under the PHS Act.¹⁴ Products that meet the definitions for drug, device, and biological product may also be classified as biological products. If you have questions regarding whether a product meets the definition of biological product or how this might affect its classification, please contact OCP.

IV. ADDITIONAL INFORMATION

For further information on the classification of products as devices, drugs, biological products, or combination products, please refer to the Frequently Asked Questions on the next page, OCP's webpage at <https://www.fda.gov/CombinationProducts/default.htm> or contact OCP at:

Office of Combination Product
Food and Drug Administration
WO32, Hub/Mail Room #5129
10903 New Hampshire Avenue
Silver Spring, MD 20993

(Tel) 301-796-8930
(Fax) 301-301-847-8619
combination@fda.gov

¹⁴ Certain biological products have been historically approved under the FD&C Act and may continue to be subject to approval under the FD&C Act until March 23, 2020. See Section 7002(e) of the Biological Price Competition and Innovation Act of 2009; see also FDA, *Implementation of the "Deemed to be a License" Provision of the Biologics Price Competition and Innovation Act of 2009*, available at <https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm490264.pdf>.

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FREQUENTLY ASKED QUESTIONS

1. Can a product be classified as a device if it exhibits “chemical action”?

Yes, if the product does not achieve its primary intended purposes through chemical action within or on the body and otherwise meets the definition of a device. However, products that meet the device definition may be regulated as drugs or biological products in some cases. See question 2.

2. If a product meets the definition for drug at 21 USC 321(g) and for device at 21 USC 321(h), how is it classified?

Generally, the product would be classified as a device, unless it falls within a special category (for example, apparatuses used in the preparation of compounded positron emission tomography drugs are classified as drugs, see 21 USC 321(ii)).

3. Can the proposed use or indication of a product affect its classification?

Yes. Two products with exactly the same composition can be classified differently based on their primary intended purposes. For example, if a vaginal product is intended solely to facilitate ease and comfort during sexual intercourse and it achieves this through lubrication that decreases friction (via mechanical/physical action) and not through chemical action, it is classified as a device. However, the same product can be classified as a drug if it is intended, for instance, to alter pH, control odor, or prevent infection, and does so through chemical action as discussed in III.B.3 above.

4. What should you do if, after reviewing this guidance, you are unsure of how your product is classified?

You should contact the Office of Combination Products (Combination@FDA.GOV) for feedback. OCP will provide you feedback, including on whether a pre-RFD or an RFD may be appropriate and what information you should provide.

5. Where can you find additional information about product classification?

Additional information on classification is posted on OCP’s webpage at: (<https://www.fda.gov/CombinationProducts/AboutCombinationProducts/ucm101496.htm>)

For additional information on how to submit an RFD, see *How to Write a Request for Designation (RFD)* (<http://www.fda.gov/RegulatoryInformation/Guidances/ucm126053.htm>).

More information about the pre-RFD process is available at <https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM534898.pdf>.

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Exhibit C

Job Description

JOB DESCRIPTION

Department/Service: Patient Services

Title: **PHYSICAL THERAPIST**

Reports to: Supervisor of Physical Therapy

Work Area: Branch Office (Nassau, Suffolk,
Brooklyn)

Position Summary:

Assesses, plans, provides and develops with the patient/client or responsible caregiver a home health plan of care for Physical Therapy, and identifies problems which warrant the placement of other disciplines and services provided by the Agency. Coordinates and evaluates the plan of care with all other disciplines providing care through the Agency, the Supervisor of Patient Services as warranted, other organizations and physicians for an assigned caseload.

Instructs patient/client or responsible caregiver in the projected care plan and expected outcomes. Provides written instructions appropriately as reinforcement of teaching and directions. Conferences with Supervisor of Patient Services or designated nurse coordinator regarding patient status, progress and discharge plan. Documents Physical Therapy skilled services in accord with Agency standards and expectations of third party payors. Obtains physician orders appropriately.

Qualifications:

Education:

1. Graduate of a Physical Therapy curriculum approved by the Council on Medical Education of the American Medical Association and the American Physical Therapy Association.
2. Current registration to practice Physical Therapy in New York State.

Experience/Skills:

1. Possesses a minimum of 1 year of satisfactory experience in a home care setting, preferably in a CHHA.
2. Knowledgeable regarding Federal, State, regulations and JCAHO standards as they apply to physical therapy services in a CHHA.
3. Demonstrates a commitment to continuing professional growth and development.
4. Good communication and teaching skills; verbal and written.
5. Ability to relate and work well with patients/caregivers and Agency personnel.
6. Ability to prioritize activities.

7. Exercises good clinical judgments in planning and implementing physician orders.
8. Demonstrates ability to analyze clinical audits and apply this to appropriate problem-solve and plan interventions.
9. Is a licensed driver with an automobile that is appropriately insured and is in good working order.

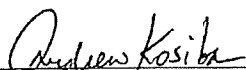
Responsibilities:

1. Represents the Agency's mission, philosophy and objectives through compassionately and competently providing Physical Therapy services.
2. Demonstrates an understanding and respect for patient rights and responsibilities.
3. Understands and applies Agency policy and procedures appropriately in the admission, treatment and discharge of patients.
4. Completes work assignment and documentation within allotted time.
5. Establishes clear, measurable goals and plan of care for the patient/client.
6. Communicates initial visit findings and the need for additional services appropriately.
7. Demonstrates ability to identify need for other disciplines in developing patient/client care plans.
8. Provides home health aide supervision according to Agency policies and procedures.
9. Records accurate information for billing, payroll and data entry.
10. Knowledgeable in Agency protocols and procedures applied to the coordination of managed care patients, benefits management for commercial insurance.
11. Projects schedule for a caseload.
12. Maximizes conferencing as a functional means through which a caseload will be coordinated, supervisory guidance will be provided and professional development will be fostered.
13. Participates in the quality improvement process and practices of the Agency to improve the quality of patient care, organizational functions, and to resolve identified problems.
14. Takes responsibility for personal professional development.
15. Performs other related duties assigned.

Functional Abilities:

(Including, but not limited to)

1. Must be able to hear and speak in a manner understood by most persons.
2. Must be able to read 12 point or larger type.
3. May lift, carry, push/pull maximum up to 50 lbs.
4. Must be able to stoop and bend; must be able to lift and transfer patients.
5. Must be able to travel to prospective patients' residences.



Employee Signature

5/19/00

Date

JS 44 (Rev. 04/21)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS

Andrew Kosiba

(b) County of Residence of First Listed Plaintiff Suffolk
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number)
Pro Se

DEFENDANTS

CATHOLIC HEALTH SYSTEMS OF LONG ISLAND, INC.

County of Residence of First Listed Defendant Nassau
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in one Box for Plaintiff and One Box for Defendant)

- | | PTF | DEF | | PTF | DEF |
|---|---------------------------------------|----------------------------|---|----------------------------|---------------------------------------|
| Citizen of This State | <input checked="" type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State | <input type="checkbox"/> 4 | <input checked="" type="checkbox"/> 4 |
| Citizen of Another State | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

IV. NATURE OF SUIT (Place an "X" in One Box Only)Click here for: [Nature of Suit Code Descriptions.](#)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES	
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice	<input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act IMMIGRATION <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 INTELLECTUAL PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 835 Patent - Abbreviated New Drug Application <input type="checkbox"/> 840 Trademark <input type="checkbox"/> 880 Defend Trade Secrets Act of 2016 SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 376 Qui Tam (31 USC 3729(a)) <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit (15 USC 1681 or 1692) <input type="checkbox"/> 485 Telephone Consumer Protection Act <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	CIVIL RIGHTS <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input checked="" type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 448 Education	PRISONER PETITIONS Habeas Corpus: <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty Other: <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement			

V. ORIGIN (Place an "X" in One Box Only)

- ☒ 1 Original Proceeding
- ☐ 2 Removed from State Court
- ☐ 3 Remanded from Appellate Court
- ☐ 4 Reinstated or Reopened
- ☐ 5 Transferred from Another District (specify)
- ☐ 6 Multidistrict Litigation - Transfer
- ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):

Title 1 of the Americans With Disabilities Act

Brief description of cause:

violations of the Americans With Disabilities Act

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND \$

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No**VIII. RELATED CASE(S) IF ANY**

(See instructions):

JUDGE

DOCKET NUMBER

DATE 12/08/2021 SIGNATURE OF ATTORNEY OF RECORDAndrew Kosiba

FOR OFFICE USE ONLY

RECEIPT #

AMOUNT

APPLYING IFP

JUDGE

MAG. JUDGE